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After breach of personal, private health information: How do you respond?

Laptop theft points to need for checklist to deal with data breach

In this digital age, a breach of personal data about clients or customers is the nightmare scenario for any business, conjuring specters of identity theft and public relations woes.

But for a research institution, the worries go deeper. In addition to financial information, a breach of data from a research project could compromise private medical information about thousands of subjects.

Then comes the decision of whether and how to notify participants about the breach.

That scenario was played out recently in Maryland when a laptop computer was stolen from the car trunk of a researcher with the National Heart, Lung, and Blood Institute (NHLBI) in Bethesda, MD. The computer contained unencrypted research information — including names, birth dates, hospital medical record numbers, and cardiac MRI data — from about 2,500 participants from an NHLBI study conducted between 2001 and 2007.

In a statement released March 24, the NHLBI's director says that the laptop was turned off and password-protected, but that the information shouldn't have been stored on a laptop computer without encryption.

"When volunteers enroll in a clinical study, they place great trust in the researchers and study staff, expecting them to act both responsibly and ethically," says **Elizabeth G. Nabel, MD**. "We at the NHLBI take that trust very seriously and we deeply regret that this incident may cause those who have participated in one of our studies to feel that we have violated that trust."

According to NIH spokesman **John T. Burklow**, the Feb. 23 theft was reported to the NIH information technology department the same day and to the NHLBI's IRB on Feb. 26. Burklow says NIH policy requires primary investigators to report to the IRB any unanticipated problems that could present a risk to subjects.

At its next scheduled meeting, March 4, the IRB voted unanimously to inform participants about the theft. On March 20, the IRB approved a letter to be sent by overnight mail to all participants for whom current

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addresses were available. Participants were told they should contact the NHLBI if they had concerns about the theft.

The letter explains the incident, points out that Social Security numbers and other financial data were not involved, and reassures participants that the theft “poses a low likelihood of identity theft or financial implications.”

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Editorial Questions

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“It is, however, an unfortunate breach of our commitment to protect the confidentiality of your research records,” the letter states.

Burklow says about 80 participants have called or e-mailed the NHLBI since the letter was sent, about a third of them expressing concern over the incident or wanting more information.

“Several individuals sent e-mails expressing their appreciation for the notification,” he says.

In the wake of the incident, Nabel says the institute is ensuring that all NHLBI laptops are encrypted, and that staff have been told never to keep patient names or other identifiable medical information on laptop computers.

In addition, Burklow says, the IRB is clarifying the notification process when a breach occurs.

Breaches common

Kirk J. Nahra, JD, a health care attorney who is co-chair of the Confidentiality, Privacy and Security Workgroup at Wiley Rein LLP in Washington, DC, says such security breaches happen all the time, in every industry.

“There’s obviously lots in the health care industry, there’s a ton in the academic community,” he says. “I take from that a couple of principles — one is that everybody’s got to pay attention to this. And a lot of what paying attention is, if it’s going to happen, what can I do to reduce the problems from that?”

Nahra says institutions need to think about the problem of data security from two angles: reducing the risk of breach and knowing what to do if one occurs.

“One question for the IRB is on the front end,” he says. “Should they be factoring security issues more into the front-end approval process? The bulk of those approval principles have typically involved privacy issues rather than security issues.”

For example, Nahra notes that laptops are stolen every day. For that reason, he says, encryption should be the norm for laptops containing research information.

“I can’t tell you it’s formally a legal requirement anywhere, but they should be doing it, and if it’s encrypted, you don’t have to worry about some of the notice issues.”

He says it’s also important to pay attention to what is being kept on laptops, and whether sensitive details such as patient names really belong on computers that so easily can go astray.

“You’re not going to say don’t use laptops,”

Nahra says. "But if we're recognizing that people use laptops and they're moving around with their laptops and there's sensitive data on them, encrypt them."

To report, or not?

Once a breach has occurred, Nahra says the institution next must decide how serious it is and what reporting is required — either legally or ethically.

He says 42 states currently have laws requiring that customers, clients, or patients be notified in the event of certain security breaches, usually involving the unauthorized release of financial information such as Social Security numbers.

Last year, California expanded its law to include medical information.

Nahra says state laws usually do not require notification if the information was encrypted.

He says the HIPAA Privacy Rule itself does not require notice to study participants if their health information is breached. But it does require that covered entities mitigate, to the extent they can, any harmful effects caused by disclosure of personal, private health information in violation of the Privacy Rule.

"Sometimes mitigation of harm would make you give notice — and it might make you give notice in situations where the state laws wouldn't," he says. "Let's say you have a security breach of [information about] AIDS patients. HIPAA might tell you to give notice even though the state laws might say you don't have to."

Nahra says an institution has to make a complicated judgment when a breach occurs to determine whether participants need to be notified.

"You have a set of incidents where you have to notify, there's another set of incidents where you should probably notify anyway and then there's a set where maybe you'll make a judgment not to," he says. "It requires an assessment every time there's a breach as to whether these obligations are triggered and what it is you're going to do."

If, for example, a laptop is stolen, but the information on it is encrypted, Nahra says an institution might make the decision not to notify participants.

Nahra usually advises clients not to have a set procedure for how to handle a breach, but rather to have a list of questions to ask first.

"Who do we notify? How do we fix it? Who do we get involved in the investigation? How do

we figure out what kind of information was involved?" he says. "It's not a one-size-fits-all response."

"If you say, 'We will always give notice of every security breach, that's not a good answer,'" Nahra says. "There's a negative to giving notice, which is you scare people. And so if there's really not a problem, don't scare people." ■

Advance directives could guide research decisions for those with dementia

Patients' preferences could be more clear

When research calls for recruiting patients with Alzheimer's disease and other forms of dementia, it's often hard to know whether patients would want to participate had they been able to make the decision themselves.

Even proxies who have been chosen to make those decisions can be uncertain whether a particular type of research should be pursued.

Some experts in geriatric research have suggested research advance directives (RADs) as a possible solution to this problem.¹

Like other types of advance directives, an RAD gives the patient an opportunity, while still cognitively capable, to make decisions about future care. In this case, the patient could detail not just whether he or she would want to participate in research, but the types of research or interventions he or she would permit.

"A person with diminished and failing cognitive capacity is different from other patients," says **Carol B. Stocking**, PhD, director of research at the MacLean Center for Clinical Medical Ethics at the University of Chicago, IL.

"With other patients, as a decision needs to be made, you can talk with them then. When they become very ill, they become more analogous to people who can no longer carry on such discussions and make decisions."

In the early stages of dementia, patients are able to make enrollment decisions. As they lose decisional capacity, proxies or surrogates give consent and patients give assent for enrollment.

She says the RADs would only provide guidance in the later decisions, which still would require consent from the proxy and assent from the patient.

While advance directives currently aren't used extensively in research, organizations such as the Alzheimer's Association (www.alz.org) have suggested them as a way to get the greatest possible input from subjects with dementia while they still have decisional capacity.

Constantine G. Lyketsos, MD, MHS, professor of psychiatry and director of the Memory and Alzheimer's Treatment Center at Johns Hopkins University and Hospital, Baltimore, MD, says that RADs can be a useful tool for certain types of dementia research.

"Conceptually I think it is a terrific idea," he says. "The time it really becomes useful is if the person is no longer able to make a decision. The real utility of a research advance directive is for research in advanced stages of the disease."

Both Lyketsos and Stocking say such directives wouldn't negate the need for a proxy or surrogate, but might give more direction as to the patient's intentions regarding research.

But they differ on the form the directive might take.

Stocking says that based on her experience, research advance directives should be very specific about the types of research a patient is considering. If possible, a patient could state willingness to be in a particular kind of study later in the progression of his or her disease.

"I would say it should be geared to the specific types of projects, and not be a general, broad consent to participate in future research," she says.

Lyketsos, on the other hand, sees greater utility in a more general research advance directive, particularly since the proxy's consent still would be obtained.

He says it's possible to outline the various types of research a person might be recruited for — genetic research, brain imaging research, etc. — but a proxy still would have to decide whether the study in question fits those general descriptions.

"There's still going to need to be someone at the time making some sort of decision," he says. "In a sense, a research advance directive is useful simply by saying that the person is generally inclined to be in research studies. That's the major utility for me."

"It says, 'I think research is important and I'm accepting of the fact that a surrogate might decide for me and these are the surrogates I would wish to appoint to make decisions,'" Lyketsos says. "That I actually think is very useful."

Planning ahead together

Stocking and her colleagues have researched a model of research advance directive that involved patients and their proxies being interviewed separately about whether to give consent for several hypothetical research projects, ranging from a low-risk blood draw to a very high-risk implantation of cells in the brain. The duos of patient and proxy then met together to discuss their choices and see where they differed.

"The patient might say, 'Yes, I would be in this research,' and proxy might say, 'Oh, but I wouldn't have agreed to it,'" Stocking says. "And they would talk, and often one would persuade the other to their way of thinking."

"We thought of it not only as a model for an advance directive, but [also] as a way of getting them to talk about the future and future research so the proxy would know better how to guide the patient or if it ever came to that, to make decisions on behalf of the patient," she says.

During the process, half the patient-proxy duos created a Planning Ahead Together (PAT) document, which, while not legally binding, was an attempt to explain and document their choices. Copies were given to the duos and were placed in the patients' files.

Patients and proxies were interviewed immediately after patients were invited to participate in research projects, and again two years after the first interview.

Of the original 149 patients, 41 had been recruited during those two years — 23 who had completed a PAT, and 18 who hadn't.

Interestingly, those who had completed the PAT didn't report any differences from the non-PAT group in the relative ease of the decision or comfort with the decision-making process.

When asked whether the PAT document had been helpful, the majority of patients who answered the question said they weren't sure, but half the proxies who answered the question immediately after having been asked to enroll in a study said yes.

Overruling decisions?

Stocking says the overall number of patients recruited for research during that two-year window was much smaller than researchers had expected. And she notes that the research that was actually proposed to the subjects during that time was also significantly different from the

hypothetical research described in the PAT. This may have contributed to the number of patients stating that they weren't sure the PAT had been helpful.

"We thought we were being very thoughtful about the kinds of research that were going on at the time we were designing the study, and it just happened that at the centers where we were doing our research, those kinds of studies were not engaged in during the research period," she says. "In fact, they were all very low-risk projects that people were invited into."

It's also possible, Stocking says, that the discussions between patients and proxies that occurred in the study — even among duos who didn't complete the Planning Ahead Together document — made the process easier for everyone and eliminated any contrast between the two groups.

In that case, might simply the act of discussing research ahead of time be as useful as an actual document? "It would be," she says.

Stocking says that much about the patient-proxy discussions surprised her.

"It was less conversational than I had imagined it would be," she says. "They said a little less, but they did talk. I remember one person said, 'I trust you. You can do whatever you want. You can make your best decisions when the time comes.'"

The research did find a small but significant minority of patients who expressed discomfort with their proxy's decision-making and who would have preferred to limit the proxy's ability to overrule the choices they made in their PAT.

"Most patients in our study wanted proxies to make enrollment decisions when the time came, even if they had disagreed about enrollment in the hypothetical projects," Stocking says. "But a minority didn't and for them, a research advance directive might help proxies and researchers make the ethically appropriate decision."

Lyketsos says that it might be ethical for a proxy to override a binding research advance directive — say, if the proxy knows the patient no longer can tolerate a procedure he or she once agreed to. But he notes that in some states, advance directives for medical care can't legally be breached.

And he raises a potential issue that could have an impact on broader use of research advance directives — whether they can be enforced across multiple institutions and IRBs.

"I think the enforceability uniformly of a

research advance directive approach would be very difficult," he says. "Because ultimately, right now, the system essentially gives all power to specific IRBs to accept or [reject] consenting processes.

"Individual IRBs are not expected to be consistent and they generally aren't," he says. "So I think that would have to be sorted out." ■

Reference

1. Stocking CB, Hougham GW, Danner DD, et al. Empirical assessment of a research advance directive for persons with dementia and their proxies. *J Am Geriatr Soc* 2007;55:1609-1612.

Translational science consortium sets out to improve IRB process

Task force sets sights on multicenter studies

A new consortium of research institutions is seeking to transform the process of translational research, in hopes of progressing more efficiently from scientific breakthrough to patient treatment.

Funded by the National Institutes of Health, the Clinical and Translational Science Awards (CTSA) have taken on a number of areas of concern, including training and mentoring for researchers and designing new clinical informatics tools.

IRBs could reap the benefit of the consortium's work as well, says **James A. Moran, JD, CPA**, executive director of the Center for Clinical Studies at Washington University in St. Louis, MO.

Moran is chairman of the CTSA's Regulatory and Ethics IRB Taskforce, which seeks to work with CTSA institutions — currently numbering 24, but set to increase to about 60 by 2012 — to come up with better ways to achieve multisite IRB review.

Because of the CTSA's goal of improving the "bench-to-bedside" process, Moran says it was an obvious choice to focus on issues raised by IRB review of multicenter studies.

"We're anticipating an increase in the number of clinical trials we're going to do, and we anticipate they will be done largely through other CTSA recipients," Moran says. "If you have 10 or 20 different sites, all academic, the IRB approval

process is a major area of interest, in terms of how long it will take to enroll your first subject.”

Faster and better

He says the task force’s goal is to find ways to break through institutional bureaucracies to better handle investigator-initiated multicenter clinical studies.

“Not only faster, but better,” he says. “That includes the quality of the research itself and also the protections given to our research participants.”

Individual institutions have received CTSA grants to work on their own ideas for improving translational research. Some of those institutions already have cited improved human subjects protection as a planned area of emphasis.

Moran says his task force hopes to take the best of those ideas and promote them across the CTSA network.

But he says the members of the task force have expressed a desire to go further.

“We’ve been talking about doing some research on the research process itself,” Moran says. “It would mean looking at practices at some of the institutions that are part of this task force and seeing what are the value-added steps, what are the high-quality things that we do, and what things maybe provide more burden than quality — burden to the investigator, burden to the institution.”

Currently, he says, the committee doesn’t have funding for such research, but Moran says the task force is looking at how they might carry it out.

In addition to his new position with the IRB task force, Moran also serves on the consortium’s Clinical Research Management Taskforce, which plans to establish a common set of measures across CTSA organizations. One of them would look at the length of the IRB approval process.

“Very soon after we start tracking in a common, consistent way how long it takes to get things done, the next question is how we can improve that,” Moran says. “I think that’s really the role of this IRB task force — to come up with some concrete things we can do based on the research and based on the available evidence.”

Articles and regulatory advice

Moran says the task force members hope to be able to publish a white paper or journal articles to help disseminate what they learn

as they examine the IRB systems at the CTSA institutions.

The task force also could work through common IRB issues arising at its member institutions.

“When we have common questions that all of the institutions are dealing with, rather than coming up with 24 different ways to do something, there could be a common approach that might be able to be replicated across institutions,” Moran says.

Beyond that, armed with data from the CTSA institutions, Moran hopes the task force could provide some suggestions to regulatory agencies to help form future guidance for other IRBs.

The IRB task force only began meeting in March and Moran concedes that it could be a while before they can achieve all of their goals.

“There are certain things that we can do fairly quickly,” he says. “If we were looking at something that an institution did particularly well as a model practice, we can get those model practices out there fairly quickly in the next six to 12 months.

“But these bigger picture things — doing the research, coming back with data, and talking to the regulatory authorities — that’s going to be a much longer time frame.”

Despite the task force’s interest in regulatory issues, Moran says IRBs shouldn’t worry that the goal of this process is more requirements for them to follow.

“The outcome here, we hope, is to come up with a more logical framework across institutions,” he says.

Although this is hardly the first effort to address issues raised by multisite review, Moran says he’s optimistic that the unique nature of the CTSA consortium can lead to success.

“The collaboration between organizations is very high in the CTSA,” he says. “I think that’s really a unique approach. Rather than just working on a problem, we’re also being tasked with getting the work done — that’s what makes us different.

“The CTSA, in order to be successful overall, is going to have to do more clinical trials,” Moran says. “We’re working on an issue that we think could be an impediment to doing that. So I think these institutions are now motivated to work together to come up with a way that we can do this better.”

For more information about the Clinical and Translational Science Awards, visit the consortium’s web site at www.ctsaweb.org. ■

Non-punitive post-IRB approval monitoring program emphasizes education

Monitoring working group makes final call

When research officials at the University of Virginia of Charlottesville, VA, began to ask what happens to a study once it's approved by the IRB, the answer became a new program: a post-IRB approval compliance monitoring and education program.

IRBs put a lot of time into approving a study, but are IRB members sure the study's protocol is being followed, asks **Karen N. Parks, RN, CCRP**, a research compliance monitor at the University of Virginia in the office of the vice president for research and graduate studies.

"Also, what resources do investigators need once they get started?" Parks asks. "And do study coordinators and principal investigators have access to the education they need?"

The best way the institution could answer these questions was by forming a separate research compliance program that is affiliated with the IRB and works side-by-side with the IRB, but doesn't report to the IRB, says **Jane Lehmbeck, RN, CCRP**, a research compliance monitor.

Compliance monitors often attend IRB meetings, and they meet with a small group of IRB members to discuss review issues and details, Lehmbeck notes.

"We read the protocol and look at the tools the study team is using to make sure they're following the protocol," she adds. "If we have questions where we didn't understand something, we might go back and look at the IRB minutes, but we generally haven't done that."

Lehmbeck and Parks explain how the compliance monitoring and education program works:

- **Studies are selected at random.** "We try not to repeat monitoring an investigator more than once a year if they've had a good review already," Parks says.

"We also will review a study if the principal investigator makes a change in the middle," she adds. "The IRB will request us to go in and review it when they approve a principal investigator's change."

The IRB also might request a review if IRB members are concerned about a problem, a viola-

tion, or questionable paperwork, Parks says.

"Once the study is selected we notify the study team and investigator and set a date for the review," Parks explains. "We review IRB files and update ourselves about the study, and we also review the IRB process."

If monitors find any problems with the IRB process or errors the IRB might have made, then they'll write a report that is sent to the IRB, Parks says.

- **The monitoring visit is systematic.** "We use a regulatory binder and look at all consent forms and select patient data to make sure patients were eligible," Parks says. "We make certain the study team followed the informed consent process properly, and we review the protocol."

Monitors also review information about any investigational drugs involved in a study.

When the monitoring visit is complete, monitors will write a report that is sent to the principal investigator, who has a chance to respond, Parks says.

- **Monitoring report data are accumulated and analyzed.** A post-approval monitoring working group that includes educators, IRB members, and others analyze the monitoring reports from the past month, looking for consistency and trends, Parks says.

They collect minimal data, including how many reviews are done, Parks says.

"The working groups tries to categorize studies into groups of exceptional, satisfactory, marginal, and unacceptable, which means serious noncompliance," she adds.

For instance, in 2007, there were 164 monitoring reviews of which 47 were exceptional, 45 were satisfactory, eight were marginal, and none were unacceptable, she adds.

This was an improvement over 2006 when of 143 reviews, 42 were exceptional, 39 were satisfactory, 19 were marginal, and less than 1% (one or two studies) was unacceptable, Parks says.

"We were excited that in 2007 there were none in the unacceptable category," Parks says.

"Basically the only situations that fall into that category of serious are those in which an investigator doesn't want to work with us at all because anyone who tries to communicate with us won't be in the unacceptable category."

The working group also makes recommendations based on the monitoring reports.

"Sometimes we see more problems with a system or department, and there are questions of whether we would handle those," she explains.

"Then the group of IRB members and educators makes recommendations, and these are sent to an IRB subcommittee."

In an extreme case, the IRB might stop a study.

If monitors find a problem that is immediate, then the vice president for research will convene a group to discuss the study and decide what to do about it, Parks says.

"We have had situations come up where we were reviewing a study and we were very concerned with safety," Parks says.

In most cases, there is time for the report to be sent to the IRB for review and comments.

"The IRB will look at notes from the working group, and if they have additional recommendations to make, they make them," Parks says. "As a final step in the process, they decide whether education is needed."

If so, the educator from the school of medicine sets up an appointment with the investigator.

A final touch is that the vice president of the office of graduate studies, which oversees the IRB, sends out letters to investigators, thanking them for their participation and summarizing the consensus of the IRB subcommittee and the working group, Parks says.

- **Educate investigators and research staff.**

"We've always touted the monitoring as educational, and it's one-on-one time with the monitor," Parks says.

"As time has gone on, we've incorporated an educator in the program, and we've done more mentoring," she adds. "We've eventually added an IRB educator who helped us do education on our web site."

The web site features voice-over slides in which people can view a brief educational session at their leisure, she says.

These are created to address trends identified through the monitoring visits.

For example, one trend noted was of investigators not obtaining surrogate consent properly, Parks says.

"So we developed a 'learning shot' about surrogate consent," she adds.

One of the biggest issues involved data safety monitoring board (DSMB) plans, Parks says.

"The IRB develops a template of how they want monitoring done and the questions they want answered," Parks says. "But what happens is a lot of people would mark these examples without reviewing them, and that was not what they intended during the study."

So the IRB has spent a lot of time educating

researchers about what a DSMB plan should be and how to fill out that template, she adds.

"We have seen improvement," she says. "Most of the errors are small paperwork errors."

The IRB educator has held several different investigator workshops in two to three hour sessions, Lehmbeck says.

These quarterly sessions are voluntary and are so popular among investigators and study coordinators that there are waiting lists.

Also, there's a mentoring program for new study coordinators or investigators, Lehmbeck says.

"A staff member will go out to the site and work with the new coordinator to see what the person needs," she explains. ■

When rolling out new forms, try this IRB's 'no-complaint' tactics

IRB focuses on marketing, educational sessions

IRB policies and forms often need to be updated and revised as human subjects research rules and regulations evolve.

But how do you create interest and buy-in to new forms?

The IRB office at Saint Louis University in St. Louis, MO, has developed a thorough and effective process for introducing new forms to staff and the research community. Calling it a "no complaint tactic to new form development," the IRB office conducted a pilot study of its process and found that it led to decreased complaints.

Last year, the IRB office had several forms, including a continuing review form and an informed consent form, to revise.

"We thought that before we did the revisions and launched the new forms we should put a systematic format in place," says **Melissa G. Fink**, MA, a behavioral and social sciences IRB manager in the department of research compliance/IRB office.

The new process was a success. Complaints to the IRB office decreased, and there was increased consistency in how new forms were processed. Also, the IRB staff received positive feedback from investigators, and communication between the IRB office and the research community improved.¹

Fink describes how the no-complaint process works:

- **Form a team to handle the project.** The IRB formed a team with members from the IRB staff, the board, and the research community.

“Then we assigned our small team and staff to make sure all necessary regulations were included in the new form,” Fink explains. “They needed to consider who was using the form and make sure the form was clear and inclusive.”

- **Pilot the new form and identify problems.** IRB staff used the form as a pilot test for IRB staff, researchers, and board members, and they made sure everyone understood the form’s terminology, Fink says.

“Once we finished the initial draft we e-mailed it and asked people to read it for comprehension,” she adds. “We asked researchers to make sure they could answer what we were asking, and we generally asked for feedback.”

The pilot test was an informal way of gathering information, Fink notes.

The form was sent to a variety of researchers, including behavioral science investigators.

“You have to select people who take the time to look at the form,” Fink notes. “A lot of time the people who were most apt to review the form were the people who were frequent users.”

Those were the research coordinators and investigators who had the most at stake in switching to new forms, so they took time to look at it and provide their comments.

- **Solicit input from the research community.** The process of asking for feedback also was a first step in obtaining buy-in, Fink says.

“It was one more area where they could see we were taking their feedback into consideration and trying to be on the same team,” Fink says. “It was one more thing that helped us form a better relationship with our research community.”

Most of the feedback involved making the instructions more clear, including word changes, she notes.

“We didn’t receive any comments suggesting a major overhaul of the form,” she says. “It was really about fine-tuning the instruments.”

Social/behavioral scientists suggested the form not use the word patient because the study participants are not patients, Fink says.

“So we eliminated the word patient from all of the forms and we use the word participant instead,” she adds.

“When we piloted the form, it was understood that we were very appreciative of any comments

or thoughts people had, but ultimately we were the authority on what would roll out,” Fink says.

“Some feedback wasn’t incorporated, but we’d get back to the person who suggested it with why we weren’t using it,” she adds. “It was very collaborative.”

Once changes were incorporated, the original team gave the form a final edit. Then the IRB manager or administrative chair would approve the changes.

- **Announce change to research community through networking.** “We notified the whole campus and research community about the new changes on the form and why we had made changes,” Fink says. “We spent a lot of time on the forms from a regulatory standpoint.”

The IRB office set dates for training sessions and advertised the dates and locations of these.

There’s an e-mail list of people in the research community, and notice was sent out through this e-mail list, as well.

“We put a notice on our web site,” Fink says. “And we made an announcement at the IRB board meetings and at IRB staff meetings.”

They notified all of the departmental scientific review committees.

“We blanketed the university with notices,” Fink says. “We mentioned the new form at any brown bag sessions that month, and anytime the IRB staff communicated with a researcher, it was mentioned.”

While past complaints had been that people didn’t know about a new form, no such complaint could be made this time around, she adds.

“We made sure we were getting enough announcements out there and enough channels out there to communicate to people, and we had three training sessions in the month, as well,” Fink says.

After one month of marketing the new form, the one-month grace period began, and the new form was placed on the IRB web site.

There were three notices sent out that month, letting people know that by the beginning of the following month the IRB office would no longer accept the old form, Fink says.

- **Train IRB staff, members, and research community.** A 30-60 minute training session on using the new forms was mandatory for IRB staff.

“We provided training at IRB meetings, taking the first 15 minutes to walk through the form for whoever was in attendance,” Fink says. “For those who were not in attendance, we sent out the form by e-mail and encouraged them to call

the staff if they had any questions.”

The education specialist provided most of the training, she notes.

“We have a medical campus and a non-medical campus, and we made sure we had training on different days and times so we could catch anyone who was interested in attending,” Fink says. “We had six sessions dedicated to the informed consent form revision.”

On average, 10 people showed up for the training sessions on the informed consent form, and about 20 people would attend the continued review form sessions.

After six announcements and six training sessions, there were few complaints, Fink says.

“We really haven’t had complaints in the last eight months, compared with what we would have faced prior to this systematic way of changing forms,” Fink says.

Also, the extensive roll-out process made it easier for IRB staff when the new forms are submitted since there are fewer mistakes because researchers and research staff better understand how to complete the forms correctly, she adds.

Now that the new form roll-out process has been developed, there will be form changes done only twice a year, Fink says.

“If we do a fine-tuning of a form, a rewording of a question, we’ll keep track of these things and then begin preparing for a June 1 or January 1 roll-out,” she says. “This is how we’ll do it for tweaks of the form, but if we had a major overhaul of a form we’d do the whole education roll-out again.” ■

Reference

1. Rich H, Moreland-Russell S, Fink M. No complaint tactic to new form development and roll-out. Poster presented at the 2007 Annual Public Responsibility In Medicine & Research (PRIM&R) Human Research Protection Programs Conference; Boston, MA: Dec. 1-4, 2007.

Investigators hold less favorable views of IRB than do research assistants

Familiarity breeds less content

An anonymous survey of investigators, research administrators, and project managers found that principal investigators and co-investigators tend to have a less favorable impres-

sion of IRBs and IRB staff than do the research assistants and project managers.¹

The study found that while all respondents had a favorable view of the IRB’s role in facilitating ethical research, investigators tended to view the IRB as a barrier to their research.¹

The people who are supposed to oversee research and have the most experience doing so, such as investigators, were the ones who had a more negative view of the IRB, says **Ricardo Cruz, Jr.**, MPH, MA, a researcher and medical student at Boston University Medical Center (BUMC) in Boston, MA. Cruz also has worked as an IRB analyst and worked in the IRB office for about six years.

Cruz conducted the study with the hypothesis that more human subjects research ethics training and experience would lead to greater satisfaction with the IRB.

But his study found the opposite: Respondents with more research experience and ethical training had a more negative view of the IRB.¹

Researchers and research staff were asked to rate the following statements¹ according to whether they strongly disagreed, moderately disagreed, disagreed, had no opinion, agreed, moderately agreed, and strongly agreed:

- The IRB does provide valuable suggestions that improve my chances of obtaining IRB approval on future protocols.
- The IRB fully understands and acts within the scope of its function.
- The IRB staff is helpful and supportive.
- The IRB does review my protocols in a timely fashion.
- The IRB does provide valuable input that improves the design or methods of my research.
- The IRB does provide a rationale for any required changes to my research protocols.
- The IRB treats investigators with respect.
- The IRB staff is cordial and professional.

Cruz theorizes that targeted human subjects research training may help to improve the relationship between the IRB and research community.

“We need more specific training, rather than training for the overall research community,” he says. “We could breakdown the training into what investigators and co-investigators should be doing and into what project managers and research assistants should be doing.”

“Everybody has a specific role in research, and so they should be taught in different groups that reinforce their different responsibilities,” Cruz

says. "That will kind of improve relationships with the IRB, and it will hammer in the actual function of the IRB and what it is."

BUMC's current human subjects educational programs received mixed reviews from the survey's respondents, he notes.

"Here at Boston University we have various educational components," Cruz says. "The National Institutes of Health [NIH] provides the first exposure to human subjects research training."

There is an on-line training mode and a didactic version in which one of the IRB chairs will teach researchers and research staff about the history of the IRB, its function, and the regulations that are followed, Cruz says.

"In addition to that we do a monthly on-line newsletter called the *Clinical Research Times*, which is specifically designed to help the research community submit protocols," Cruz adds.

It's an up-to-date newsletter that delineates various policies, he says.

When study respondents were asked which training they found the most satisfactory, their top pick was the NIH training, Cruz notes.

"That makes sense because that's their first exposure [to human subjects research], and it's very detailed training," Cruz says.

Survey respondents gave positive views of the IRB's newsletter, he says.

BUMC's human subject protection training on-site was ranked the lowest, and attendance rates for those sessions were low among those who responded to the survey.

IRBs and IRB staff have a difficult job trying to satisfy everyone and turning around protocols quickly, he notes.

"When I was working at the IRB, analyzing protocols and turning them around, you'd have people who were very satisfied and would drop you a quick e-mail, saying, 'thank you for your timely response — you were very helpful,'" Cruz recalls. "And then you'd have people who no matter how long it took you were not happy."

At BUMC, the IRB worked to improve investi-

gator-IRB relationships by inviting investigators to come to the meetings, Cruz says.

"We'd discuss the protocol while they were outside the room and then bring them into the meeting to see if some issues could be addressed at the meeting," he says.

One of the reasons why investigators might have a less favorable opinion of the IRB than do their research assistants could be the result of their being less involved with the studies on a day-to-day basis, Cruz suggests.

"It seems like the problem is that many investigators take on many studies, and it's questionable how involved they are on a day-to-day basis," he says.

This is another reason why targeted educational sessions are necessary.

"It all comes down to subject protection, and if investigators aren't overseeing the day-to-day function of a study, then it's kind of hard to see

CE/CME Objectives

The CE/CME objectives for *IRB Advisor* are to help physicians and nurses be able to:

- **establish** clinical trial programs using accepted ethical principles for human subject protection;
- **apply** the mandated regulatory safeguards for patient recruitment, follow-up and reporting of findings for human subject research;
- **comply** with the necessary educational requirements regarding informed consent and human subject research.

Physicians and nurses participate in this medical education program by reading the issue, using the provided references for further research, and studying the questions at the end of the issue.

Participants should select what they believe to be the correct answers, then refer to the list of correct answers to test their knowledge. To clarify confusion surrounding any questions answered incorrectly, please consult the source material.

After completing this activity at the end of each semester, you must complete the evaluation form provided and return it in the reply envelope provided to receive a letter of credit. When your evaluation is received, a letter of credit will be mailed to you.

COMING IN FUTURE MONTHS

■ Investigator attendance at IRB meetings might benefit some IRBs

■ Experts discuss issues with "vetting" PIs

■ National Cancer Institute explains best practices for biospecimen use

■ Interactive informed consent has potent benefits

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CE/CME questions

17. When considering whether to inform subjects about a data security breach, an institution must consider:
 - A. applicable state laws.
 - B. HIPAA's obligation to "mitigate harm" from a possible disclosure.
 - C. ethical obligations to inform.
 - D. All of the above
18. A patient with dementia who completes a research advance directive still must appoint a proxy or surrogate to make decisions about inclusion in individual research projects once he or she has lost decisional capacity.
 - A. True
 - B. False
19. Which of the following results were reported after the roll-out of a post-IRB approval monitoring program at the University of Virginia at Charlottesville?
 - A. There were no unacceptable reviews in 2007.
 - B. Exceptional reviews increased from 42 to 47.
 - C. Marginal reviews decreased from 19 to 8.
 - D. All of the above
20. In a recent survey of researchers and research staff's opinions of a university medical center's IRB, who ranked the IRB the least favorably?
 - A. Project managers
 - B. Research coordinators
 - C. Principal investigators
 - D. IRB members

Answers: 17. (d), 18. (a), 19. (d), 20. (c).

whether project managers or research assistants are dealing with the subjects appropriately." ■

Reference

1. Cruz R, Woodson J, Allensworth-Davies D, et al. Is there a correlation between human subjects research training and satisfaction with the IRB? Abstract presented at the 2007 Annual Public Responsibility In Medicine & Research (PRIM&R) Human Research Protection Programs Conference; Boston, MA: Dec. 1-4, 2007.