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An essential resource for managers of clinical trials

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IN THIS ISSUE

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Research organizations improve QI with electronic data collection

Consistency, efficiency, reliability are chief aims

When research organizations establish quality improvement and auditing processes, the chief aims are to improve consistency and efficiency in identifying and preventing noncompliance. One way to do this is through use of an electronic data collection tool.

"We had been using an Excel spreadsheet for reviewing compliance, but we were missing things," says **Paula Bistak**, RN, MS, CIP, CHRC, executive director for human subjects protection program at the University of Dentistry and Medicine (UDMNJ) of New Jersey in Newark, NJ.

The institution already had a long-standing quality improvement (QI) program for auditing investigators, but its IRB auditing was less established and formal, so the institution worked to create an electronic form that would make these audits consistent, systematic, efficient, and comprehensive, Bistak says.

They developed the solution, a smart form using Microsoft InfoPath 2007, after holding brain-storming sessions with information technology specialists and research program auditors.

"We came up with an auditing tool that would be consistent, and we did that with limited staffing," Bistak says.

It's important to have an auditing tool that could be used by both experienced and novice auditors, she adds. "We wanted to use this so we could go through our routine faster."

"What we wanted to do was develop a procedure that was systematic, comprehensive, specific, measurable, and efficient," says **Cheryl A. Forst**, RN, BSN, CCRP, senior compliance analyst in the human subjects protection program at UDMNJ.

"We set out to develop a system to expand our program, and we needed to do it on a zero budget," Forst adds.

The result met all goals, Forst says.

The team of analysts and informatics specialists created a form that used Microsoft InfoPass, a smart form, that provides drop-down choices that can be molded according to institutional needs, she explains.

"In order to make a form that's measurable we had to include quantifiable questions and identify trends," Forst says. "We did audits prior to

visiting investigators, and if we saw a trend, say they were missing an IDE annual report when they were doing device studies, we'd let them know they were missing documentation in their file."

For example, the electronic tool's section on adverse events includes these questions:

- Are reviewer sheets attached to each report of internal/local SAE/UAE as required?
- Are reviewer sheets signed and dated?
- If the IRB has requested clarifications/follow-up of individual SAEs/UAEs, has each request been appropriately reconciled and documented with PI response and IRB review?
- If an SAE/UAE requires change to current informed consent document, has the revised consent been reviewed, documented, and processed appropriately?
- Is each report in the IRB protocol file appropriately entered into the IRB database?

A poster based on the tool received a first place award when it was presented at the annual meeting of the Society of Research Administrators International in October, 2008, in National Harbor, MD.

Here is how the tool works:

- It's simple to use: The electronic form is color-coded and has check boxes. Auditors answer questions sequentially, Bistak says.

"The boxes turn red or yellow depending on how critical the information is," Forst says.

"So if you have a study that had funding listed, and they forgot to tell you who the funding source was, the box turns red so you'd know it was a piece of information that you tell the IRB director was missing," Forst explains.

The electronic tool is in XML format so any university could have access to it, Forst notes.

The form has conditional formatting, optional and repeating sections, she adds.

Auditors use laptop computers, taking these on their audits, Bistak says.

Most of the electronic tool's questions have "yes" or "no" answers, but some are open-ended questions, Bistak says.

"If you answer 'yes' it'll take you down another trail," she adds. "If something is missing, it takes you down another set of questions."

The electronic tool's questions cover every aspect of a study and its IRB review, and the tool has pull-out sections that inquire about risk, Bistak says.

"The tool uses plain text and is readable," Forst says. "We used our own platform to design it, and it was independent — not tied to any other programs in the university."

The form makes it as easy as a click at the corner to replicate a box that needs to be repeated, such as continuing review box, and it can self-populate when repetitive information is needed, Forst says.

"When you enter something in the box, it has your drop-down choices, asking you what kind

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of review this is – a full board, expedited, or exempt review," Forst says.

"It's a very easy to use form that many institutions have and many research administrators can use," she adds. "If they like this form in any institution they can pick any Smart Form and create it, molding it according to their institutional needs."

• Shorten form for efficiency: "We found out in the testing phase that the form was very time consuming," Forst says. "It was okay for smaller files, but when you had a protocol study that consisted of 10 or more files it would take three hours to complete that form."

Initially, auditors thought this was fine, and they'd be able to audit every file, but they quickly decided a shortened version would be more practical.

"It's a very manageable tool," Bistak says. "We have 3,000 active studies over all of our campuses, and the auditors don't have hours and hours to review all of these studies."

While the review is useful in conducting for-cause audits, its real value is when the office wants to conduct targeted audits, such as reviewing principal investigator-sponsored studies or asking a specific question, Bistak adds.

"So the whole form is shortened up," Forst adds. "We took away the fields we didn't need."

If an auditor clicks on devices off the "view" section of the toolbar menu then she can click on "devices," and the form automatically will remove all the areas that do not pertain to device studies, shortening the form, Forst explains.

"So mainly it goes to study population, approval information, sponsor, and funding source, and the next box would be IRB determination," Forst says.

It will ask these kinds of questions:

— Is the device recorded on the sheet?

— What is recorded?

— Was there a serious risk with the device?

"Then it asks a couple of pediatrics and vulnerable population questions, and that's mostly what you need to do for that audit," Forst says.

With the short form, auditors can pull all protocol files of a particular type, such as those with pediatric subjects who are wards of the state or investigators holding INDs, Forst explains.

The long form still is used as needed.

"It's just that initially it seemed like a great tool to use to review every file, and that proved to be very time consuming," Forst says.

"So we decided to do it according to categories, tests, or areas that we consider hot topics," Forst adds.

• Generate reports from tool: "The final goal was to generate reports, and that's where we are now," Forst says.

"We can forward information to IRB directors to use for the purpose of educating their staff," Forst says.

"We're not doing any trend reporting yet," Forst notes.

But the electronic tool can be used for a variety of reporting purposes.

With help from the informatics technology experts, the form can put information into different folders where it can be used to identify trends and issues, such as missing information, Forst says.

"We make sure files are complete so if we had an external audit we wouldn't be caught with missing information," she adds.

If an audit reveals that an investigator has issues in a particular area, then the findings could lead to a corrective action plan, Bistak notes.

"Part of the reason for using the electronic form is to let investigators or even the IRB know we're not being arbitrary in what we're looking for," Bistak says. "We show them that this is what we checked, and we want to do it the same way each time because investigators are sensitive to being singled out – so it's the same for everybody." ■

Study cites importance of patient self-reports

Oncology patients' AE reports studied

Patient self-reporting has been successfully used for purposes of evaluating quality of life, satisfaction with care, and looking at symptom end points in clinical trials, but questions have remained about whether or not patient self reports are useful in collecting adverse event data.

One new study has found that the answer is an enthusiastic "yes."

The study asked for symptoms reports by lung cancer patients receiving chemotherapy and compared their reports with those made by their clinicians for six items pertaining to the National Cancer Institute's Common Terminology Criteria for Adverse Events (CTCAE).[1]

Researchers found that clinician CTCAE assessments were better at predicting unfavorable clinical

events, such as emergency room visits and death, but that patient reports provided a better assessment of daily health status.[1] **(See story about study's findings and implications for CR, p. 17.)**

"The method of what we call patient-reported outcomes (PROs) is very well-established and quite widespread in research," says **Ethan M. Basch**, MD, a medical oncologist with Memorial Sloan-Kettering Cancer Center in New York, NY. Basch is a co-author of the study on using PROs for adverse event data collection.

"This is really a new application of that approach with some methodological and technological refinement," Basch says. "I do think it's feasible to implement this strategy on a widespread basis because we can improve our understanding of the toxicities."

The recent study is part of a broader research program of looking at patient self-reporting, Basch says.

"We're looking to standardize the approach," he adds.

Both clinician reports and patient reports provide useful information, Basch notes.

"The final model remains to be fully developed," he says. "This is really a methods paper that describes the usefulness of information provided by patients and clinicians."

One possible drawback to relying on patient self-reports is that patients might have a low ceiling for their self-report ratings because they haven't had enough experience to put a particular symptom into perspective, critics suggest.

For example, a patient might rate his pain a 10 out of 10, saying this is as bad as it can be, while the clinician would rate it an eight, knowing from experience that the patient's pain will get worse.[2]

This argument involves response shift or recalibration, which suggests a patient might change his or her orientation about severity based on context, Basch says.

"So when first starting treatment a patient might have one perspective about what the worst thing that could happen to him could be, and that could change," he explains. "In the setting of controlled clinical trials, the ultimate context for these approaches, these sorts of shifts are accounted for and presumably balanced between arms."

Also, the severity of the response shift is an important dimension of the patient's self-report of their experience, and it's not captured by the clinician because he doesn't have the benefit of a changing perception, Basch adds.

"While it's true there's a response shift and clinicians have an overview of how bad things could be, that likely leads clinicians to downgrade the severity of patients' symptoms based on how bad they think it will be," he says. "And that's probably an unfair downgrading of patients' symptoms at any one point in time."

Just as a very complex host of phenomenon contribute to a patient's self report, there also is a very complex group of factors contributing to a clinician's report, Basch says.

"This may include contextualizing a patient along a continuum of patients that the clinician has seen," he says.

For example, a clinician's context could change his or her report of the following:

- Is the patient particularly stoic?
- Does the patient overstate severity?
- Does the patient's health status make him or her ineligible for a trial?

"The final methodological piece is that it's important to have a mechanism for minimizing missing data," Basch says.

"One could imagine that patients who are particularly ill might not report as regularly, and we don't want to bias our data as a result of that," he explains. "So we have to have back-up data collection methods."

A back-up method could be using an automated telephone system to call patients regularly, screening for adverse symptoms, Basch says.

"If a patient doesn't answer there's a second call, and for the third call a nurse will call the patient," he adds. "If the patient still doesn't respond then the nurse might call a family member because the patient is in trouble."

When cost is a consideration, clinical trial sites could use inexpensive technologies, such as Web sites that harness the patient's own telephones and computers to collect the information.

"It might save in cost because the time spent by physicians in eliciting and abstracting adverse symptom information could be transitioned over to the patient's side," Basch says. "And if one uses electronic data capture this information would be directly imported into a research database."

The electronic data capture via Internet would work by having an Internet-based questionnaire available on a touch screen in which the patient would log in and enter his or her own toxicity information. It's then sent directly to the electronic database, he explains.

"We've been doing this research now for six to seven years, and we have found that patient familiarity with self-entering data by computer

and telephone has changed fundamentally," Basch says. "So many of us do our banking via automated telephone systems or computers, and we get movie tickets this way, so these are ubiquitous technology."

Investigators who fear their patients might not want to use the technology for self-reported outcomes should know that their patients likely already are exchanging this kind of information with each other online through support communities, he adds.

"Particularly patients who are elderly and frail are very comfortable with using this technology to report their own health information," Basch says.

The benefits of using new technology to collect patient reported outcomes outweighs the risks pertaining to patients' discomfort with the technology or potential security issues, he says.

The logistics and security systems can be designed to ensure only the patient responds to the questions, Basch says.

"If the security of these technologies is satisfactory for the banking industry, it probably should be satisfactory for this context as well," he adds. "We have the opportunity to harness patients' enthusiasm for this information and improve the efficiency of clinical trials and quality of information." ■

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Patient self reporting for CR is trend expected to grow

Pain, quality of life, now AEs all collected

As clinical research continues to show the benefit of using patient self-reporting, investigators and clinical trial sites should expect to see this practice expanding and improving.

As one recent study shows, patient self-reporting is not necessarily a substitute for clinical reports, but it can enhance and improve the overall data collected.

Investigators enrolled 163 lung cancer patients and their clinicians, asking them to independently report on the adverse symptoms of fatigue, pain, nausea, vomiting, diarrhea, and constipation.[1]

The study found that patients tended to report worse severity and incidence of symptoms than clinicians, and patients tend to report adverse symptoms earlier in the course of their care. This suggests that drug labels that are based solely on clinician reports are underestimating the frequency and severity of AEs as compared with patients' perspective.[1]

This difference was due to clinicians being more attuned to patients' trajectories to major disease benchmarks, while patient reporting better reflected real-time suffering, the study shows.

The study's authors concluded that the perspectives are complementary and both should be included in clinical trial results.[1]

When clinical trial investigators begin to ask patients routinely for information about adverse events, they'll be following a trend in recent years that is shifting focus to patient self-reports, notes **Ethan M. Basch**, MD, a medical oncologist with Memorial Sloan-Kettering Cancer Center in New York, NY.

For example, investigators previously used physicians' reports when collecting information about patients' pain.

"That is not the case anymore," Basch says. "Now we look only at what the patient reports, and the same is true with the quality of life reports, where the gold standard is the patient's point of view."

One day, researchers might routinely ask patients about their adverse events.

"This paper suggests the clinician's view also provides useful information," Basch says.

The National Cancer Institute (NCI) has sponsored an initiative that would have a standardized item bank of adverse symptom questions that could be used in clinical trials, Basch says.

"The first step is to institute a questionnaire administration approach so patients could answer toxicity questions on a regular basis at clinic visits or between visits, either electronically or on paper," he explains.

A second step would be to administer symptom questions used in phase II studies to get a sense of specific adverse symptoms in a particular population, he adds.

"There would be broad screening for a lot of

items in phase II, and then more in-depth screening about specific items in phase III and post-marketing research," Basch says.

A shared model of toxicity reporting could be developed, he adds.

"I suspect the ultimate model that will be developed is patient self-reported information that is then relayed to clinicians and investigators," he says. "And the final report of toxicities for documentation and regulatory purposes will be filed by the clinician with the benefit of the patient's perspective."

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Managing CR staff requires finesse, attention to details

Job can entail managing outside PIs

Sometimes the most difficult aspect of managing a clinical research organization or a research office in a university is dealing with the various investigators working together in difficult deadline scenarios.

"When you're dealing with faculty pulled in so many ways, the most difficult part is getting things done on time, or getting them done early," says **Elsa G. Nadler**, EdD, director of grants development at the University of Toledo in Toledo, OH. Nadler spoke about how to best manage faculty at the 2009 Society of Research Administrators (SRA) International Annual Meeting, held Oct. 17-21, 2009, in Seattle, WA.

"The other most difficult issue is getting all of the required subcontract paperwork done," Nadler adds. "All universities have some standard documents that they want back from anybody who is going to be a subcontractor on a project, and obtaining these on time sometimes can be a little difficult."

For example, if an investigator at a different institution plans to do a significant portion of the research work in his own laboratory, then that investigator has to meet all of the same regulatory requirements as the institution that is the leader in the project, she explains.

"And the investigator has to send the paperwork to us in time for us to complete the entire package," Nadler says. "The deadline might be the first of November, but I need his stuff two weeks before then."

"There are a lot of details involved, and every agency and sponsor has a different set of rules and requirements," he says. "I've gone through 70 to 80 pages of text to make sure everything is correct."

When dealing with an organization's own staff, a research director or manager typically should have a good understanding of the various personalities involved and how they work together, Nadler suggests.

"You have to know what their past history is, how they get along with each other, and who does or doesn't play nicely in the sandbox," she says.

And when conflicts arise, a manager needs to know who to go to for help.

For instance, there might be a situation where a brainstorming session is hijacked by one investigator, jeopardizing the group's ability to meet its goals. This is where a manager needs to go to his or her supervisor and request assistance in repairing any damage that's done.

"So part of the solution is knowing who you can go to for help, especially when you see something is not going as smoothly as it could," Nadler says.

"Sometimes you have to smooth ruffled feathers, and sometimes you simply have to be assertive and say, 'Look, this is what we're going to do,'" she adds. "But there's also a great deal of straightforward organization involved in doing something like this."

Organizing tasks and roles can help prevent personality issues and deadline problems. Here are some of Nadler's suggestions for how research organizations can improve the process of meeting deadlines while managing a variety of personalities:

- Create lists with dates and details: "I keep two lists; one list is made of pieces of the whole proposal and the ideal dates," Nadler says. "The other list contains details, like biosketches, current funding."

The biosketch has a two-to-four-page description of the person's professional background, as well as their current and recently completed research projects, she adds.

"Some agencies ask for information about studies that were closed within the past three years, and some ask for information about stud-

ies that were submitted, but not awarded yet," Nadler says. "The list can become extensive, depending on the sponsor."

The biosketch also might include a list of collaborators, she adds.

"I create a template and send it out to everyone so all of the biosketches look uniform and present a coherent picture," Nadler says. "These have to be done for each research grant proposal."

Nadler's proposal list includes each piece of what is needed for a research project, such as a project description, equipment description, resources, and abstract.

• Use a timeline to track deadlines: It's important to keep a research project well-organized, tracking who is responsible for what and by which deadlines, Nadler notes.

"I like to create a timeline, and I like to be sure everybody who is a partner in the project knows what they're supposed to do," she explains.

The timeline includes tasks and persons responsible and dates when the tasks should be done. When each person involved completes a task, it's checked off the list, Nadler says. "When I get a biosketch from someone, I can check them off my list."

Having a timeline that lists responsibilities and deadlines makes it easier to remind investigators of what's needed.

"If I haven't gotten something within 24 hours of when I'm supposed to receive it, then I send out a general reminder by email," she says.

• Deal quickly as problems arise: When a problem arises or a deadline is missed, Nadler quickly notifies the researcher involved.

"I send an email or pick up the phone if I have to," Nadler says. "I'm good at reminding people that I haven't gotten what I need from them."

University faculty often miss deadlines because of their full schedules, so this is an ongoing issue, she notes.

"When it gets down to the wire, I get a little nervous, and I tell them we have to move on this project," Nadler says.

University research directors often have to deal with faculty from other institutions since increasing numbers of research projects are collaborations between investigators from different institutions. This complicates things, Nadler says.

Research directors have to make certain outside researchers follow all of the university's rules and requirements, as well as the state and federal regulations, she says.

"The university I came from had a policy whereby if the proposal wasn't in the central office by a certain date, the policy said there was no guarantee it would get submitted," she adds.

"Every university I'm aware of requires faculty to have their chairs and deans sign off on a proposal," Nadler says. "The reason is because the proposal really is a legal document, and the faculty member is not the awardee, the institution is." ■

Compliance Corner

Promoting an ethical culture might succeed where rules fail

Compliance requires understanding

Research organizational leaders sometimes forget that it takes more than firm written rules and guidelines to create an ethical and compliant clinical research atmosphere.

Clinical research leaders need only to look at media attention paid to research problems and noncompliance over the past decade to realize that good intentions do not always lead to good results.

"In some respects, compliance challenges have been made easier by the fact that we've had a lot of attention paid to a lot of important compliance areas over the last couple of years," says **Kristin West**, JD, an associate vice president for research administration and the director of the office of research compliance at Emory University in Atlanta, GA. West spoke about the elements of a strong compliance program at the 2009 Advancing Ethical Research Conference, held by PRIM&R [Public Responsibility in Medicine & Research], Nov. 14-16, 2009, in Nashville, TN.

Academic and medical research organizations now can see the value that's added to having strong compliance programs: institutional reputations are at stake, West notes.

Examples of ethical breaches have made headlines in medical research, as well as in government, corporate business, and Wall Street investments in recent decades.

"There's a fabulous code of business ethics from 1990, describing a company that you'd want

to work for just because of all the thinking that went into this code. But this was Enron's code of ethics," says **Elizabeth Heitman**, PhD, an associate professor in the Center for Biomedical Ethics and Society at Vanderbilt University Medical Center in Nashville, TN. Heitman spoke about creating a culture of compliance at the recent PRIM&R conference.

The Enron Corp., whose very name is synonymous with pervasive corporate fraud, had the right kinds of compliance rules, but lacked a culture of conscience and integrity among its leadership, Heitman says.

"They'd done all of the work that lays out what the code of conduct should be, and they had an internal component of ethics for employees to follow, but the company was rotten at the top," she explains. "And being rotten at the top meant the body couldn't survive."

Enron ended up with a reputation not for excellence, but as a punch line to a joke, Heitman adds.

Institutions that have strong compliance programs with safeguards in place are less likely to be the subject of long-term public interest even when something goes wrong, West suggests.

"It loses a lot of sex appeal as far as the media is concerned, and the same goes for audits and investigations," West adds. **(See story on making an airtight compliance program, p. 21.)**

"No audit or investigation by a regulatory agency is ever going to be perfect," West explains. "But if you can show you have tried to predict and put in place processes to eliminate those findings, then you're going to get a lot of credit for that if you have an FDA inspector monitor show up."

Research organizations likewise need a strong sense of leadership about how to do excellent work with integrity, Heitman says.

"Everyone needs to be working for a common goal, and there needs to be compliance policies that work, not policies that drive people crazy," she adds.

For example, if a research institution requires detailed documentation and justification of every travel expense and expects staff to complete these items on paper, as well as electronically, then the institution may be inviting noncompliance.

"An onerous method of completing required paperwork discourages people from doing it right," Heitman says.

Another self-defeating practice is to have administrators treat employees like they're untrustworthy and arbitrarily restricting their activities regardless of its correlation to actual compliance goals.

This creates an atmosphere in which employees feel the institution is unfair, and this feeling of unfairness can lead to noncompliance, Heitman notes.

"A study by Brian Martinson, Melissa Anderson, Lauren Crain, and Raymond de Vries found one of the most important predictors of misbehavior by researchers was the sense that the environment they worked in was not fair," she says.[1]

Institutions that too rigidly or too inconsistently enforce compliance rules run this risk.

"People might feel the rules are unfairly imposed on them or that the administrative structures of their institutions don't really fit their work, or that other people are allowed to get away with things and they are not," Heitman explains. "This is the kind of culture in which people may begin to cheat or maybe just begin to interpret the rules in their favor in order to level the playing field."

For example, researchers already spend a big portion of their time attending to documentation and administrative duties, so institutional leaders should be sensitive to this and not impose unnecessary additional documentation requirements.

It's a fine line between paying careful attention to the good stewardship of resources, which is what compliance offices are about, and creating burdensome documentation demands, Heitman says.

When compliance policies are burdensome then employees will seek shortcuts or will procrastinate, both of which could lead to noncompliance, she adds.

Another counterproductive strategy institutions sometimes take is to create policies that reflect all regulatory rules and organizational guidelines and then have employees sign copies to show they have read them, only to drop the subject after that, Heitman says.

University officials might think the institution is off the hook once it has employees sign the rules document, but what it might be doing is creating an atmosphere in which people believe compliance is a signature and not a process.

This type of hands-off approach might send the message of "We need to get this done, and we don't care how you do it," Heitman explains.

The key to avoiding these types of institutional dangers is to create a culture of compliance through words, action, and deeds.

"The idea of making it easy to do the right thing is also to make it easy for people to want to do the right thing," Heitman says. "Employees

should want to make their institution proud, to work at a place they're proud of, and to have the rest of the world know they do good work here."

These feelings of pride come not just from high publication rates or obtaining grant money, but from a collegial atmosphere in which no one wants to find a different job, and everyone else wants to work there too, she adds.

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Take concrete steps to strengthen compliance

Beefing up compliance P&Ps

There are two major fears when it comes to a research organization having a potential compliance breach, and these are unpleasant findings during a regulatory audit and bad publicity.

Clinical research directors who wish to avoid both of these outcomes need to beef up their compliance programs, starting with a hard sell to institutional leaders, an expert suggests.

"Before you can get somebody to go along with your program and follow rules, you need to show them what is the added value for them," says **Kristin West**, JD, an associate vice president for research administration and the director of the office of research compliance at Emory University in Atlanta, GA.

"Show them the names reported in the paper, and show them how you have policies in place to deal with these problems," she adds.

Here are some suggestions for improving your compliance program:

1. Freshen up, improve standard operating procedures (SOPs).

Solid SOPs will help immensely with audits, monitoring visits, and compliance issues.

"Show FDA inspectors or monitors your SOP, saying 'This is our SOP, and this is how we handled the case,'" West says.

Then when the auditors or monitors respond positively to the site's SOP, share this outcome with staff, she suggests.

"So people understand why we wrote the SOPs and included these items in it," West adds. "They'll see that people actually do care about this."

Writing practical and strong SOPs is a first step.

"Take concrete steps to improve your compliance program, and once you have those steps in place, and they're successful then the next round is easier," West says.

2. Do a risk assessment.

CR directors and compliance officers should identify their biggest risk area and the probability of a problem happening in connection with this risk, West advises.

"Consider damages, including reputational damages, if something goes wrong in that area," she says. "After you pick one of these areas and say this is a huge area of risk, then you have to determine the concrete steps the organization can take to eliminate the risk."

West gives an example of an issue at Emory of having employees who were minors working in the laboratories.

"A lot of folks want to come here to get experience through a mentorship, or they have a friend who works in the lab, and they also want to pursue a career in science," West explains.

"This obviously is a huge risk area – having young people in high school working in the lab," she adds. "We want to encourage it because this is an educational institution, and we want young people interested in these careers."

But it's the university's responsibility to make certain these underage staff/students are safe while they're at the institution.

This required a concerted effort to improve policies and procedures involving both the lab and handling minors who are working for the institution.

3. Have a group assist in identifying risk.

A thorough risk assessment might require a group effort.

For instance, an organization could form an oversight committee or a forum to discuss research risks.

"Fortunately at Emory we have a very nice forum for doing that, an enterprise risk management forum," West says. "Each year we look at the various risks to the institution across the board, and we prioritize those risks and have risk process [managers] who come up with corrective action plans to address those risks."

Emory's forum is well attended by institutional presidents, executive vice presidents, risk management staff, and general counsel, West says.

Risk process managers are responsible for reporting back to the forum whether a particular action worked, she adds.

"It's so high level, and you have vice presidents taking time out of their day attending these meetings, so people realize it's important and put it at the top of their to-do list," West says.

4. Include all stakeholders in developing a corrective action plan.

Look at the whole area and think about who should be involved, West advises.

For the laboratory and minors example, stakeholders would include the environmental and safety unit staff, as well as academic units that run programs for high school students and mentoring programs, West says.

The environmental and safety unit staff, for instance, are responsible for getting lab staff their personal protective equipment and training in using it.

"We have insurance and risk management folks who are big stakeholders, and we have a general counsel office there because you need a certain amount of legal language," West says.

For a risk that involves university students, another stakeholder might be staff from the campus' student union or campus life program.

5. Delegate and ask for help.

"If you have a group working on this you can delegate tasks, asking if anyone is hooked up with any groups or list serves where they could email people for ideas of how to handle the risk area," West suggests.

Also, an Internet search might reveal ideas and solutions.

"You should delegate this to different members of a stakeholder group, and then have a meeting and come back to develop policies and procedures," West says.

One strategy is to appoint one person to be the draft person who will take the information collected and then write a draft to be shared for feedback, she says.

"You take ideas from the meeting, and a lot of times at our university, we have a template we use for all standard university policies, so you know if you want a policy adopted that it has to have these particular elements," West explains.

When a policy is created or another type of solution is found then it will need to be approved by upper level administration, she says.

Since all stakeholders were included in discussion of the risk and solutions, the top administrators will know that all necessary staff buy-in already has been obtained, she adds.

6. Communicate and train staff on new policies and procedures.

"You will need to communicate policies to staff and train people on what they need to do," West says. "This could be done in a meeting with administrators at different departments, through posting information on Web sites, and by going to faculty meetings."

The key is to make sure all staff involved with handling issues related to the risk area are aware of how they should handle the situation under the new policies, she adds.

Typically, a new policy will include a follow-up protocol that lists who is responsible for this policy.

"That owner is responsible to make sure the policy is working, and the owner should come up with an auditing and monitoring plan," West says.

In the example of how the institution could handle having minors in the lab, the owner of the policy was the environmental health and safety department, she notes.

"They provide follow-up on questions regarding the policy, looking at various protocols to see who is working on them," West says. "They also conduct physical lab inspections and see firsthand who is working in that lab and whether lab employees are wearing personal protective equipment." ■

Clinical Research News

ResearchMatch has successful launch

ResearchMatch, the new Web site that will link potential research volunteers with clinical trial sites, has more than 50 institutions enrolled.

The initiative is a Clinical and Translational Science Awards (CTSA) project that is funded by the National Center for Research Resources, part of the National Institutes of Health. It is powered through the National Library of Medicine.

The CTSA program is led by the National Center for Research Resources (NCRR), and it's a part of the National Institutes of Health (NIH).

ResearchMatch has the simple goal of bringing together people who want to find research studies and investigators who need to find people to

participate in their studies, according to the Web site at researchmatch.org.

The disease-neutral, not-for-profit registry is free and secure, and one of its stated purposes is to prevent studies from ending too early because of a lack of volunteers.

As of the end of 2009, 53 institutions were part of the ResearchMatch Network, and this represented 41 of the CTSA members.

ResearchMatch asks potential volunteers to register and provide some basic information that could be used to match them to a study. Researchers use this information to find a good match for any particular study.

The new Web site serves as a complementary site to NIH's clinicaltrials.gov Web site, which lists thousands of clinical trials. Through clinicaltrials.gov, potential volunteers can seek out a particular trial that interests them, and they do not have to register to learn more about enrolling studies. ■

AAHRPP accreditation at 200 sites by end of 2009

AAHRPP extends period to 5 years

The Association for the Accreditation of Human Research Protection Programs (AAHRPP) of Washington, DC, had accredited 200 research organizations by the end of 2009.

AAHRPP's board of directors also voted to lengthen the period between reaccreditations to five years instead of three years, beginning Jan. 1, 2010. However, newly accredited organizations will continue to have three years before they must be reaccredited.

Spectrum Health in Grand Rapids, MI, and South Shore Hospital in South Weymouth, MA, were numbers 199 and 200. Other newly-accredited organizations include HealthPartners Research Foundation in Minneapolis, MN, the University of North Carolina at Chapel Hill in Chapel Hill, NC, Independent Investigational Review Board Inc. of Plantation, FL, and Liberty IRB Inc. of DeLand, FL. The 200 accredited organizations represent nearly 1,000 entities, according to a news release by AAHRPP.

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Another change that went into effect on Jan. 1, 2010, involves the annual reporting procedure, according to AAHRPP. The board voted to revise its annual reporting procedure to request more specific information changes in program scope, changes in program delivery, and catastrophic events, an AAHRPP news release says.

For more information go to the association's Web site is located at www.aahrpp.org. ■

CNE/CME Objectives / Instructions

The CNE/CME objectives for *Clinical Trials Administrator* are to help physicians and nurses be able to:

- **explain** pertinent regulatory mandates
- **develop** practical clinical oversight strategies;
- **discuss** best practices shared by facilities that successfully conduct clinical trials.

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

- Check out these billing compliance audit forms
- Targeted therapies, personalized medicine CR is poised for growth
- Improve CR site productivity with better negotiated budgets
- Here are strategies for improving recruitment
- Debate continues over continuing experimental treatments when CT is over

CNE/CME *questions*

1. Which of the following questions about adverse events should not be asked on an electronic auditing tool?
   A. Are reviewer sheets attached to each report of internal/local SAE/UAE as required?
   B. If the IRB has requested clarifications/follow-up of individual SAEs/UAEs, has each request been appropriately reconciled and documented with PI response and IRB review?
   C. If an SAE/UAE requires change to current informed consent document, has the revised consent been reviewed, documented, and processed appropriately?
   D. All of the above could be asked

2. A recent study of cancer patients found that patient self reports of adverse symptoms provided a better assessment than clinician reports of which of the following?
   A. Emergency room visits
   B. Deaths
   C. Daily health status
   D. All of the above

3. Research administrators or directors who manage various principal investigators might find it useful to create a biosketch of investigators. Which of the following information would it be useful to include in a biosketch?
   A. The PI's professional background and current and recently-completed research projects
   B. The PI's personal background, including family and marital status
   C. A complete list and copies of published studies
   D. All of the above

4. Which of the following would be the best strategy for thoroughly assessing an institution's CR risks?
   A. Have a compliance officer write an outline of all possible risks
   B. Hold an enterprise risk management forum in which an organization's leaders brainstorm
   C. Email similar institutions for ideas
   D. None of the above

   Answers: 1. D; 2. C; 3. A; 4. B.