CLINICAL TRIALS
ADMINISTRATOR
An essential resource for managers of clinical trials

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IN THIS ISSUE

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Special focus: research management

[Editor's note: In this issue of Clinical Trials Administrator, *we are focusing on best practices in managing research and clinical trials, including the cover story on how to improve quality and efficiency through a centralized research office, and inside stories on best practices in improving clinical operations, training research coordinators, and hiring and firing staff.]*

Children's hospital saves time, money through centralized services

Investigators, sponsors, patients all benefit

Medical and research institutions that centralize clinical research services can help physician investigators improve study quality and efficiency and save money through better budgeting, an expert says.

Connecticut Children's Medical Center in Hartford, CT, made a decision to centralize clinical research services several years ago, and the result has been well worth the expense and effort, says **Lisa Benson**, CCRP, manager of research administration and finance.

The centralization of services has resulted in research budgets that typically are right on target, and it has helped physicians without research experience get involved in studies they might otherwise not have attempted, Benson says.

Also, since one coordinator handles most of the IRB submissions, there's efficiency in that process, Benson notes.

"The coordinator knows the format the IRB likes and the language they want, and it helps prevent study delays," Benson says.

The IRB approval process typically takes about six to seven weeks but, even when contingencies are required, these are sent back to the IRB promptly and are quickly approved, she adds.

The medical center, which is almost 11 years old, has about 50 ongoing studies that are handled — at least in part — by the centralized clinical research team of nine, Benson says.

"We have centralized services where one division does the regulatory documents, preparation for all 1572 financial disclosures, licenses, and all of that," Benson says. Other members of the centralized research services staff include these disciplines:

• a clinical laboratory technician who reviews laboratory manuals for various studies and knows how to work with research studies;

• an administrative assistant dedicated to clinical research trials;

• five clinical research coordinators — three who are full-time and two part-time; they are trained and experienced in conducting trials and IRB submission;

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Editorial Questions

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• a manager who reviews study budgets and can assist with contract negotiation, which is Benson's role;

• a clinical manager who provides compliance oversight, with regard to participant registration and billing procedures.

The medical center supports the managers on the team, but the study coordinators' salaries have to be covered by research projects, Benson notes.

"When we started, we had a staff of three," Benson says. "So we've grown in the past four years."

Benson offers this example of how centralized services can improve the budgeting and contract negotiation process: "We had a physician new to research who negotiated a study budget on his own, and a check was sent to this office," she says.

"I didn't know anything about this study, so I contacted the investigator and said 'I'd like to review the budget and contract,'" Benson says. "I found that his budget was $50,000, but when I calculated the budget I came up with $135,000."

So Benson called the sponsor and told them the physician had come up with the budget on his own without looking at all of the hidden costs.

"The physician had planned to use his clinic nurse, who sees all of the patients, and she didn't have time to do this study, too," Benson says. "There was no way she'd be able to carry out her regular duties and complete this study."

Under Benson's budget, the study would require a research coordinator, and there was a fee budgeted for IRB services, both of which were missing from the doctor's budget.

Once the sponsor reviewed Benson's proposal and saw the revised study budget, the sponsor agreed that the higher amount would be necessary to do the study and they paid it, Benson adds.

If the doctor had proceeded on his own, as would have occurred without the centralized services, he wouldn't have been able to complete the study as budgeted, Benson says.

"When I did a review, I sent it over to a statistician," Benson says. "His sample size was off, and he never would have gotten the answer to his question."

The investigator doctor was grateful for the help, and the institution and sponsor were both better off with the revised budget.

Benson offers this advice on how to centralize clinical research services:

1. Obtain buy-in from the top.

At Connecticut Children's Medical Center, the

director of research operations realized there was a need to have research projects handled through a specific area for better compliance and other reasons, Benson says.

"Institutions are under such a microscope now for compliance and making sure they follow the good clinical practice," Benson notes. "When dealing with pharmaceutical companies, it makes sense to give contracts to experienced people to review."

Plus, physicians have such high demands on their time in the clinic that there's little time left for research, she adds.

"So we felt that if we could give them the help and tools they need then it would help them carry out research," Benson says.

One reason it was not a hard sell to the medical center's leadership was because the centralized services area started small with only three institution-supported salaries, Benson says.

2. Introduce concept to physicians.

Benson and the clinical manager visited the various hospital departments to introduce the centralized services to physicians and others.

"This gave us an opportunity to find out what was going on out in the institution," Benson says.

During meetings with physicians, Benson and the clinical manager would ask them what research they were doing, if any.

Then they'd tell them, "If you'd like to be involved in research, this is what we could do to support your research so you're not doing it on your own," Benson says.

They'd say, "There's no reason for you to do IRB submission and contracts with sponsors because we can do that for you," Benson says. "Many investigators didn't know that institutional officials could sign contracts, and once they learned we were here to support them, we began receiving more and more research protocols that investigators wanted to do."

So physicians would call the centralized research office when they were contacted by pharmaceutical companies and ask for assistance with research contract negotiations and budgeting.

"Soon, more and more people started to use us, although we still had one or two investigators who were a little fearful about losing control," Benson recalls.

If an investigator wants to do a study but doesn't have the necessary resources in his or her clinic, then the centralized office will provide the staff and assistance needed.

"I believe there is overall efficiency in study management now, whether it's for doing case report forms or administrative support," Benson says.

Even the physicians who thought that using the office would result in a loss of control or a monetary loss have been won over to the concept of centralized research services and are using the office for studies, she notes.

"They find their studies are budgeted much more appropriately, and they're getting the dollars they need to cover all study costs," Benson says. "And the contract negotiations take into consideration all of their interests, including publication rights."

There still are some departments that have their own dedicated research coordinator, and these typically are areas where the research is highly specialized, such as pulmonary, gastrointestinal, and hematology/oncology, Benson says.

"So those research coordinators are not housed with us and they're not paid by us," she adds.

But even in these cases, investigators often use the centralized office for other services, including budgeting, contracts, etc.

3. Train research staff.

The institution has staff take the Collaborative IRB Training Initiative (CITI), which can be found online at www.citiprogram.org. CITI provides education in human subject protection for biomedical and social/behavioral research.

Everyone involved in research is required to take CITI training, Benson says.

"And we urge our coordinators, within two years after they're hired, to obtain certification, usually from SoCRA," Benson says.

Investigators also have to take CITI courses, which the institution pays for, Benson says.

The education is required, and if they haven't completed the courses, then their research proposal will not be processed by the IRB, she says.

4. Provide ongoing outreach.

"When new clinicians are hired, we get contacted, and we put it on our calendar and schedule appointments with them and bring them materials about the clinical trial unit and centralized research," Benson says.

"We'll ask the new clinicians whether they've done any research in the past and which areas they're interested in researching," Benson explains. "We ask if they would like us to contact them about trials in their areas of expertise."

The centralized office has assisted in encouraging six new investigators to begin research in the past two years, she adds.

"I think if institutions can set up a centralized

research office, then it helps the institution stay in compliance, and it provides support to investigators who would like to do research but don't have the time and resources to do it," Benson says. "From the sponsor's perspective, it minimizes their time on the site, and we keep hearing from the sponsor that the centralized office is 'great.'"

The centralized office has helped to strengthen sponsor-trial site relationships, and it's helped patients and their families by enabling the institution to offer more research using cutting-edge technology and state of the art medicine, Benson says. ■

Expert offers tips to improve operations

Here are four best practices

Before a sponsor company, a research institution, or a clinical trial site expands and grows, managers should think clearly about the organization's culture and plan accordingly, an expert advises.

"One of the things that smart companies do is think clearly about what their organization's culture is before they make a decision about how big the clinical operations will be," says **Laurie Halloran**, MS, CCRA, president and chief executive officer of Halloran Consulting Group of Brighton, MA.

"What I see as progressive companies are those starting to think about the business, versus just the science, as an important aspect of clinical operations," Halloran says.

The companies that gain the biggest benefit from clinical operations are those that have a primary focus and vision on high quality and efficiency, she adds.

For instance, pharmaceutical companies historically have been therapeutically oriented with isolated teams working on one disease entity, Halloran explains.

"There was little cross-fertilization between teams," she says. "Now, they're realizing they need to think horizontally and not act like 10 different small companies where nobody ever talks to each other."

Halloran offers these best practice suggestions for implementing such a change:

1. Show support from the organization's top managers.

This type of philosophical change requires support from top management for a process of mandating quality, training for quality, building an infrastructure for quality, and encouraging cross-department communication, Halloran says.

Academic research organizations, like the traditional pharmaceutical company, could also benefit from this type of philosophical change, she says.

"Scientists are not trained or encouraged to work collaboratively, but are trained to experiment independently," Halloran says.

Collaboration between departments is a very different philosophy than the individual experimentation habit, and it means that an institution would need to embrace business practice, including program management, cross-functional processes, and top-down supported training, she says.

"So the number-one best practice is to foster and support from the top an operations function that centrally ensures quality, as well as efficiency," Halloran says.

2. Make the most of the regulations' broad application.

"I steal the quote, 'Skating the gray,'" Halloran says. "Regulations are very black and white, but they're also very broad."

The research industry has gotten bogged down in thinking it can write up a process or procedure that interprets every single situation; it doesn't work, Halloran says.

"People get stuck and are drowning in the process," Halloran says. "What 'skating the gray' really means is an organizational adoption of principles of critical thinking, problem-solving, and training of those skills."

The goal is to interpret regulations to fit a situation while still remaining true to the practices and regulatory intent.

For example, a compliance auditor comes up with findings in an audit that are applicable only in specialized circumstances, Halloran says.

"Rather than training the team how to think through the business and regulatory impacts of the issues, the compliance department rewrites the standard operating procedures (SOP) to cover the remote likelihood of this incident happening again," she explains. "The outcome of this is that people either continue in a noncompliant way or they drown in the process."

The problem is that many people working in a research organization do not know what the regulations actually say, Halloran says.

"They think, 'We've always done it this way, and so it must be in the regs,'" she says. "One person told me, 'We have to write in the third person because it's in the regs.'"

Federal regulatory officials often say at national meetings that "less may be more," meaning that research organizations should look at what the situation is and analyze where it could impact patient safety or data quality, Halloran says.

"They should document where those issues have been dealt with and not create 1,000 pieces of paper just because everything has to be written down," she adds. "You have to apply wisdom to problem solving."

Too few people have those skills, and they're so concerned they will make a mistake that they take compliance beyond what is necessary, Halloran says.

"This causes compliance departments to say, 'If we cover every eventuality in the SOPs then people will follow it,'" Halloran says. "But it doesn't work that way, so the business strangles under the weight of cumbersome SOPs."

3. Keep it simple.

"Another best practice is to keep documentation simple and to teach problem-solving, and hire with an eye toward the wisdom that comes from experience," Halloran suggests. "Don't make the SOPs a substitute for training and knowledge."

For example, an organization's SOPs might include this line: "A monitor must document all communications, including email, faxes, and letters," Halloran says.

"Just the fact that it says you must document all communications exponentially increases the paperwork," Halloran says. "But if youchanged it to say, 'A monitor must document all significant communications,' it simplifies it dramatically."

The key is that staff must be trained to understand what "significantly" means in this context.

"The people writing SOPs write them more complex because it's a quick fix in their minds," Halloran says. "They think that if you write a 35-page SOP then people have to follow it — but it doesn't have to be this complex."

4. Plan ahead instead of reacting.

"Very few organizations ever are given the luxury of having time to plan," Halloran says. "This is very closely interwoven with not knowing what happens from above."

Many organizations react rather than being proactive due to a lack of top-down communication that is clear, concise, and complete, Halloran notes.

"There's a general perception among the avenues I travel that information is withheld from management and staff levels of organizations because there's a lack of understanding about how much the big picture would help them in their planning," Halloran says.

"We all run around so busy and so frantic that we lose the benefits planning would give us to rest and reflect while we consider the best practices that we can adopt," Halloran says.

Planning includes two important elements regarding staffing an organization:

• Make sure you have the right people in the seats on the bus, Halloran says.

"A lot of people make the mistake of needing a body to fill a spot and then settling for a person who kind of meets the criteria," she says. "Then they're always suffering because of that choice, and this is true of virtually every organization I know — there are people who should never have been put in the positions they're in."

This is the essence of the saying that bureaucracy is created for the purpose of dealing with incompetence, Halloran adds.

The key is to hire people who have the ability to solve problems, communicate well, and be flexible and proactive, Halloran says.

These qualities should be a higher priority than the technical skills, because those skills are more difficult to teach staff, she says.

"But then you have to invest in the training," she notes.

• Training is essential, Halloran says.

"Some people think training should be a luxury instead of a necessity," Halloran says. "But no matter what level a person is in, ignorance is much more expensive than education, and that's from a Chinese fortune cookie."

Organizations try to contain costs, and so managers decide to cut training first without regard for the overall organizational impact of that decision, Halloran says.

"Some organizations are adopting technology that has some value, but it will never replace what a live educational program does to give richness and group wisdom to an organization," Halloran says. "It's, overall, a short-term gain financially, but a long-term loss organizationally." ■

Training program offers best practices

Initial training lasts all day

Research coordinator training is an area that often is short-changed at institutions.

The traditional way education is done for clinical research staff could be labeled a baptism by fire, says **Joan Bardsley**, RN, CDE, MBA, an assistant vice president for scientific affairs at MedStar Research Institute (MRI) in Hyattsville, MD.

MedStar Health is the largest provider of health care in the District of Columbia/Baltimore, MD, area. The research institute is a part of MedStar Health and supports research throughout the system, as well as employing researchers to conduct research.

"When we first got into the practice of looking at research coordination training, we found very few published best practice models," Bardsley says.

Research sites either hired staff with experience, and could count on these individuals to get to work immediately, or they had to provide more extensive mentoring to people who did not have much experience, she explains.

When credentialing became available for these disciplines, MedStar Research Institute managers thought it would be very important for research coordinators employed at the institute to meet the high standards set by the Association of Clinical Research Professionals of Alexandria, VA, Bardsley says.

"We felt we needed to do something as an institution to support those credentialing efforts, so we did surveys and came up with a comprehensive program, including a preceptor program and ongoing training," Bardsley says.

Here's how it works:

• **New coordinator training:** "We have new coordinator training where any coordinator new to MedStar, and that includes those who are not just new by experience, is required to take an all-day coordinator education course," Bardsley says.

The course covers the basics of good clinical practice (GCP), as well as these other topics:

- introduction to clinical research and GCPs;
- informed consent;
- practical approaches to IRB submission;
- drug and device accountability;
- ethical considerations in clinical research;
- recruitment and enrollment;
- data collection;
- principal researcher responsibilities and study team responsibilities.

The training also introduces new staff to employees in other departments.

"The program evaluations we've received about the new coordinator training have been positive," Bardsley says. "The new employees like getting together, and they've offered suggestions for other topics to include."

• **CITI program:** The Collaborative IRB Training Initiative (CITI) offers basic human subjects protection education and allows institutions to post additional instruction materials specific to their own organization.

"The second piece is the CITI program, which is well known in the research arena for offering training," Bardsley says.

"We wrote modules that are customized to research at MRI. Our employees take basic core CITI modules, plus 12 of our own modules," she says. "This ensures they're going beyond the basics."

Each module takes 20 to 30 minutes to complete, and there are 20 to 30 modules in all, she says.

"They do this during their work time, but we recommend completing them over several days to avoid burnout," Bardsley says.

Research coordinators are required to take all of the modules, she says.

• **Preceptor program:** The preceptor program is in the development stage, but several of the MedStar centers are piloting it, Bardsley notes.

The idea is for every research coordinator to have a preceptor when he or she is hired. The preceptor might not be a supervisor but will be someone responsible for ensuring that a set criterion of tasks and expertise is offered to every coordinator, Bardsley says. **(See clinical research coordinator/preceptor checklist, p. 31.)**

Preceptors would have an inclusive checklist of tasks, responsibilities, and competencies for the new hire, and the preceptor would be responsible for ensuring the new employee performs as appropriate for the position, she says.

The next step will be to formalize the preceptor program and train employees in how to be a preceptor, she adds.

• **Ongoing training:** MedStar has monthly training sessions, except during the months of the all-day coordinator training.

The ongoing training sessions include a lecture on a topic that is new, pertinent, or requested by the coordinators. The hour-long lecture is given in

MedStar Research Institute
Clinical Research Coordinator/Preceptor Checklist

Name of CRC: Name of Preceptor(s):

Content	Reference	Preceptor	CRC	Date
MRI Overview	Receive Barnett Self-Instructional Curriculum			
	Review & identify resources located in MRI website			
	Receive NHA Avenue Telephone/Dept Listing			
	Acknowledge Location and Content of Standard Operating Procedures			
Administrative Policies	Location of copier/fax/mailbox			
	Location of computer files on MRI network			
	Telephone/Voice Mail Access			
	Weekly Tracking Meeting (if applicable)			
	Study coverage/back-up			
	Timesheets-Accounting Units & Activity Numbers			
	Pager/On-call responsibilities			
Clinical Trial Start-Up	Confidentiality Agreement			
	Site Qualification Visit			
	CV & Medical Licenses			
	Protocol			
	Financial Disclosure			
	Applicable investigator agreement documentation: (1572 (drug); Investigator Agreement (device); Statement of Compliance (other)			
	Protocol Signature Page			
	Lab Normal Ranges & Accreditations			

Chart source: Joan Bardsley, RN, CDE, MBA, Assistant Vice President for Scientific Affairs, Acting Director of Office of Research Integrity, MedStar Research Institute of Hyattsville, MD.

a group setting, or it can be Web-based, Bardsley says. It's held about eight times a year, she says.

The institute tried video conferences, but these didn't work well, so they have switched to a Web-based program . All of the slides are archived, so participants can review them at a later date for reference, Bardsley notes.

Some recent sessions included these topics:
- changes in IRB regulations and IRB processes;
- how to prepare for an audit by the FDA;
- feasibility and cost analysis of clinical trials;
- ethics and human subject protection in research.

• **Evaluate training programs:** "We're very interested in job satisfaction and quality of research," Bardsley says. "We're trying to see if the outcomes of these interventions and programs make a difference, and we're looking at the concept of studying it, although we don't have a formal outcome measurement program in place."

There are evaluations and questionnaires given to coordinators, and from these administrators learn what coordinators need in their training, she notes.

"We try to learn from experience, as well as outside resources," she says.

"When we first began training, we often found that the programs weren't strong or structured enough," Bardsley says. "So we've tried to put in place a strong, systematic, programmatic education program for coordinators that is for both initial and ongoing training."

The goal is for the training program to help the institute with professional growth and to help staff with job satisfaction and best practices, she adds. ■

Best practices for hiring, firing, managing staff

IRB office serves as role model

No clinical trial site or research institution is immune to problems when it comes to hiring and firing staff.

Yet, this is an area that sometimes fails to make it to the top of the priority list.

An IRB office manager has devised a strategy that employs best practices in hiring and managing staff, and office turnover has been reduced as a result.

"You have to have a clear idea of what you need in a position before you go out and recruit someone," says **Tanna MacReynold**, CIP, an institutional review office assistant director at Fred Hutchinson Cancer Research Center in Seattle.

Managers need a clear idea of what a position's duties are, and they need to work in coordination with human resources departments, whenever this is possible, MacReynold says.

"And you need to be open to looking for people outside the box," MacReynold says.

By this, she means that sometimes it's job applicants' inherent qualities, such as dedication and ability to work with a team, that are more important than their specific skills.

If a manager looks for the basic people skills and ability to learn that are necessary for a job, then the person they hire may be just the right job candidate, even if they need additional training in the specific skills of the position, MacReynold says.

MacReynold says she has learned through trial and error that it's also important to look for cues or an intuitive sense about a job candidate's dedication and ability to stick with a new job despite the inevitable obstacles the person will encounter while being trained for the job.

So while she's had a few incidences in which the people hired did not last long, her staff, for the most part, have remained constant, and morale is high, MacReynold says.

Here are some of the managing staff and hiring best practices MacReynold recommends:

1. Carefully screen every applicant for your job priorities.

In some research positions, including IRB staff jobs, it can take three to six months to train a new employee to both learn the job and learn the policies and procedures of the research institution, MacReynold says.

So with that kind of investment necessary, it's crucial to screen candidates for potential commitment to the job and organization, she says.

"If someone was hopping around from job to job every year, then I don't consider that person to be a potential candidate," MacReynold says.

For organizations that have a human resources department, this would be the most efficient way to eliminate the definite 'no's.' The HR staff could pre-screen candidates, eliminating those applications that do not meet a manager's basic qualifications or the ones that have red flags that the manager outlined to the HR staff earlier, she says.

MacReynold further screens applicants for commitment and their ability to handle a heavy workload.

She explains to applicants that the workload is very difficult for many people to handle and, perhaps, they would like to speak to a current employee about it or even come in on a work day to observe someone who has that same position.

This is a strategy she's developed after suffering a few failures: "I've literally had people who were here for no more than three months and who came from good backgrounds who said, 'I didn't get this workload,' and they've left," MacReynold says.

"So it's really important for us, as managers in screening and interviewing people, to get the message across about the complex nature of the position," MacReynold adds.

2. Assess candidates for strong teamwork and people skills.

"It's not just important to know what skills a person comes in with," MacReynold says. "A lot of people can learn the tasks, but the ability to fit in with the group is as much, or more, important to me."

It's a good idea to have a human resources manager and a person who currently holds the position for which candidates are being interviewed to

sit in on job interviews, MacReynold says.

The other people observing the interview might have questions of their own, or they might have observations about the applicant's experience and ability to work with a team, she notes.

Once the interview and applicant process has narrowed the potential new hire field to a few candidates, then MacReynold will invite the candidates in to meet the rest of the staff.

"The staff can give us feedback on what kinds of hits they got off this individual during the questioning, and they can ask the person questions, too," MacReynold says.

MacReynold has also learned from experience that the job candidate who cannot offer the name of a current or past supervisor as a reference probably isn't a good match for her office.

3. Use a probationary period wisely when it's time to make a staff change.

It often takes only a few months for managers to realize they've made a mistake in hiring someone, and when this happens, it's best if there's a probationary period in which the person can be let go.

"It's critical to help the person either become a good match, or if you can't, then act quickly because it's a real drain on the office morale, and work is not getting done," MacReynold says.

Also, during the probationary period after someone is hired, there should be regular meetings where the new employee is provided feedback and the opportunity to discuss problems.

"I try with my new folks to have weekly meetings," MacReynold says. "There are no wrong questions, and I let new employees know that and meet with them on a regular basis to help them succeed and to give them feedback along the way."

Each meeting with employees should be documented, so there is a written record of any problems and how they were addressed, she adds.

Occasionally, the new employee can be given additional tools with which to learn their job, or they can be placed with a mentor among the more experienced staff, she says.

Other employees often will let MacReynold know when there are problems with a new employee, but they also are willing to help this person improve and give him or her a second or third chance, MacReynold says.

They just want to know that the new employee and management are working on the problem, she adds.

4. Manage ongoing staff issues, including morale problems.

"Having a strong team investment of 'You're not in this alone, but you're in it as a group,' helps with morale," MacReynold says.

Positive feedback also helps keep morale high, but a manager should know each employee well enough to determine whether the person would like public or private praise, group or individual recognition, she notes.

"I learned a lesson from the HR department when there was an individual who didn't feel like I gave him any positive feedback," MacReynold recalls. "So I went to HR and said, 'I don't understand; I give them feedback and tell them they're doing a good job, and I do this in a staff meeting.'"

The HR manager asked MacReynold what that one individual needed, and it then occurred to MacReynold that the employee wanted individual attention and positive feedback.

"Some people want a more direct compliment, and it's the management's responsibility to know your staff well enough to know what works for that individual," she explains. "Other people hate to be told in public that they are doing a good job, and they don't like to be out in the limelight."

MacReynold also takes small measures to improve morale, including giving birthday cards to each employee.

"One of the key things is to know your staff and what it takes to help them be positive about their jobs," MacReynold says.

A more important way managers can improve staff morale is by giving employees a role in the decision-making process, so they will be invested in decisions and feel comfortable providing their input, MacReynold adds. ■

Compliance Corner

OIG official's ideas for improving site's compliance

Federal guidelines expected this year

Research institutions have paid greater attention to compliance and oversight issues in the past decade, partly because of national and Congressional attention paid to corporate wrongdoing by Enron and other non-research institutions.

But what's missing from the headlines is how much work goes into creating an effective compliance program.

The main purpose of a compliance program is to bring together administrative activities that ensure a program is run with integrity in the financial, administrative, and ethical realms, says **Peggy Fischer**, PhD, an associate inspector general for investigations in the Office of the Inspector General, National Science Foundation in Arlington, VA. Fischer spoke about effective compliance programs at the 2006 Annual Meeting of the Society of Research Administrators of Arlington, VA, which was held Oct. 14-18, 2006, in Quebec City, Canada.

"So when you look at compliance programs, which come from government rules and regulations, you need to ask, 'How does the person who is in charge of that ensure the programs that are their responsibility are operated ethically so employees can work in an environment that's safe and ethical?'" Fischer says.

The Department of Health and Human Services, Office of Inspector General, published in the Nov. 28, 2005, *Federal Register*, draft OIG compliance program guidance for recipients of U.S. Public Health Service research awards.

That guidance was put on hold after research institutions responded with comments requesting universal guidance that would apply to all agencies from which they receive federal funding.

This request was forwarded to the Committee on Science, National Science and Technology Council, and the White House Office of Science & Technology Policy (OSTP), which have been working with other federal agencies on such guidance since the summer of 2006. The office has guidance that is being finalized among the various agencies that would be affected, and when it has been approved by all, it will be published in the *Federal Register* as a draft available for comments.

While the HHS draft guidance provides good examples of financial management and compliance, the expected OSTP guidance will cover a full range of compliance issues, including human subjects review, animal welfare review, and others.

The draft could be published as early as the spring of 2007, but is expected at least by the end of the year.

Research institutions do not need to wait for federal guidance, however, because there are many best practice ideas and models available for improving compliance.

One way to ensure an ethical and compliant research program is to examine at-risk areas, Fischer suggests.

Ask these questions:

- What are the things I do that are the most risky?
- Where do I have the weakest controls?
- What are the things that go on that I don't know anything about?

Research compliance managers should take a close look at the black hole projects that are under someone else's control, Fischer says.

"That's a risk area that you need to know more about," she adds. "So the objective of a compliance program is to provide some insight that will reduce the level of risk associated with the institution."

Fischer recommends that compliance programs refer to the Federal Sentencing Guidelines for Institutions, which identify seven key elements in a compliance program. They are, as follows:

1. implementing written policies and procedures;
2. designating a compliance officer and compliance committee;
3. conducting effective training and education;
4. developing effective lines of communication;
5. conducting internal monitoring and auditing;
6. enforcing standards through well-publicized disciplinary guidelines;
7. responding promptly to detected problems and undertaking corrective action.

When institutions run into trouble with compliance regulations, they can be asked to settle with the government, and this might include both a monetary amount to repay alleged wrongdoing and an agreement to implement a compliance program, Fischer notes.

It's wiser for institutions to be proactive and have a comprehensive compliance program in place before they are snared.

"The rationale is that you'd rather do the compliance program yourself, so when federal officials come in you could say, 'I've got one, but we just had an odd incident,'" Fischer explains.

The most common types of civil/criminal allegations, according to NSF OIG investigative files from 1990 to 2006, are the following, according to Fischer:

- theft/embezzlement - 31%;
- false or fraudulent statements - 24%;
- miscellaneous - 20%;
- false or fraudulent claims - 13%;

• conflicts of interest - 9%;
• computer fraud - 3%

And the most frequent audit findings are these:

• policies and procedures inadequate or absent - 24%;
• lack of source documentation to support costs - 18%;
• inadequate system to track, manage, or account for costs and/or assets - 14%;
• unallowable costs - 7%;
• lack of proper approval, certification, or authorization - 6%;
• inadequate or absent project or technical report - 6%;
• reconciliations inadequate or not performed - 4%;
• inadequate or absent financial report or proposal - 4%;
• costs claimed exceed amounts or rates allowed by award provisions or federal regulations - 4%;
• lack of segregation of duties - 4%.

In the best case scenario, an institution never has a civil or criminal finding from a government investigation because the institution's own compliance program would help to prevent fraud and abuse, discover all problems, and correct them immediately.

"The objective is to make sure the incident doesn't happen again and that you can detect civil or criminal wrong-doing from the government's perspective," Fischer explains.

The key is to have an active internal oversight and auditing program in place, Fischer says.

"An independent program is an extremely good way to catch potential problems when they're small," Fischer says. "Programs like that can catch issues in internal controls, such as not having sufficient independence between check-issuing and check-signing."

Also, money-flow problems can be caught and corrected with these types of programs, she says.

"Make sure you have a good employee education program so people know that compliance is a priority from the top of the organization on down," Fischer says. "The leader of the organization must articulate it, believe it, and live it."

Part of compliance also includes creating an environment in which employees feel they can report something of concern to administrators, and this reporting will not be seen as a negative action on their part, Fischer adds.

"You can't have a compliance program if there's no support for it at the top," she says.

Lastly, all compliance programs should include annual training sessions for teaching staff how to handle conflict of interest issues, reimbursements, and reporting of problems, Fischer says.

"Are there brochures around the institution saying, 'This is our hotline?'" she says. "How do you handle the nuts and bolts of your job according to policies and procedures?"

Each training program should be tailored to the institution's particular needs, Fischer adds. ■

CE/CME Objectives / Instructions

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

- **review** pertinent regulatory mandates;
- **develop** practical clinical trial oversight strategies;
- **review** 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

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CE/CME *questions*

7. When writing standard operating procedures (SOPs) for a research organization, one expert recommends "skating the gray." What does this mean?
A. Write SOPs that are comprehensive, thorough, and able to anticipate every contingency and problem that could occur.
B. Don't write a policy to interpret every single situation or that interprets regulations narrowly. Instead write a flexible policy that relies on staff to use critical thinking and problem-solving skills to interpret the policy and find appropriate solutions.
C. Copy the regulations verbatim into SOPs.
D. None of the above

8. When creating a course to train research coordinators, which of the following topics would not be a good fit?
A. Introduction to clinical research and good clinical practice.
B. Practical approaches to IRB submission.
C. Drug and device accountability.
D. All of the above would be suitable

9. According to Tanna MacReynold, which of the following is the best strategy for finding an ideal candidate for a research job?
A. Look for a candidate who exhibits a high level of commitment to a job and who has the necessary job skills, as well as skills in dealing with people, juggling a heavy workload, and working on teams.
B. Find a candidate who has the precise job skills needed and who is accustomed to work autonomously.
C. Hire the person who has the best recommendations and who is the most punctual for the interviews.
D. None of the above

10. According to data from the National Science Foundation (NSF) Office of Investigator General (OIG), the most frequent audit findings, during investigations of research organizations, are which of the following?
A. Theft/embezzlement, false or fraudulent statements, conflicts of interest.
B. Computer fraud, inadequate reconciliations, absent project report.
C. Policies and procedures inadequate or absent, lack of source documentation to support costs, inadequate system to track, manage or account for costs and/or assets.
D. None of the above

Answers: 7. (b); 8. (d); 9. (a); 10. (c)