CLINICAL TRIALS ADMINISTRATOR

An essential resource for managers of clinical trials

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CR sites can survive & thrive despite poor economic conditions

Here is some expert advice

The clinical research industry has hit another economic low point as the economy continues to falter and there is little chance of further economic stimulus money for research through a renewal of the American Recovery and Reinvestment Act of 2009 (ARRA).

Academic research institutions are suffering from losing interest income from investments, federal grants are down, and even industry-sponsored trials are harder to come by. All of these factors have made it very challenging for research sites to maintain projects and staffing, experts say.

"Everybody has to deal with this; obtaining federal funding is getting increasingly difficult," says **Brian C. Springer**, MHA, executive vice president of Roswell Park Cancer Institute in Buffalo, NY. Springer formerly was the executive director of research and business administration at Alvin J. Siteman Cancer Center at Barnes-Jewish Hospital and Washington University School of Medicine in St. Louis, MO.

"It's been harder to get money from many sources we traditionally used to fill in the gaps from extramural funding," Springer says. "These include philanthropy and endowments, which are starting to come back in value, but are still challenged due to stock market declines."

Many different research institutions have had to cut their workforces in the past two years, although things are slightly cheerier than they were in 2008, Springer says.

CR sites find they have harder studies, less studies, and less staff than what they once had, says **Wanda Kay North,** PhD, MBA, RN, CCRC, CIM, manager of The Center for Clinical Research at St. Joseph's/Candler Health System in Savannah, GA.

"That's a lot of pressure on the manager and staff, as well," North says. "I have to expect more and more from my staff, and sometimes it's difficult to explain to them that they'll have to enroll subjects if they want to keep their jobs."

CR managers have to toe a fine line between pushing for the highest productivity, retaining staff, and maintaining morale, North adds. *(See story on best practices in retaining staff, p. 89.)*

Managers also have to convince higher administration that the CR office needs to maintain staff in order to generate the funds that will keep research going.

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"If you're not involved in the research world you don't understand the magnitude of the work that goes into research," North says. "It takes trying to educate the higher administration about what exactly it is you do in the office so they won't just see the dollars, but will see the work that goes into getting those dollars."

All of this requires a focus on communication and education.

Clinical research sites now live in a post-ARRA world.

"ARRA helped to add or maintain jobs, but now it's pretty much over," Springer says. "Institutions that were set up based on some level of projected growth in resources, even with a diversified portfolio, have not had adequate funding to sustain their operations at the same level."

Plus, Medicaid payments are down in many states where legislatures are enacting across-the-board cuts to balance budgets, and Medicare reimbursement may face challenges in the long-term.

"Many of the ways we have traditionally funded research have been strained or reduced or both," Springer says. "Many of us look to the National Institutes of Health or the National Cancer Institute, but those budgets have not grown and, in fact, are losing purchasing power."

If there's a federal government shutdown in August, as the congressional impasse over the budget seems to suggest, then even more bad news might be coming.

Given all of this gloom and doom, what can a clinical trial site do to stay economically viable?

CR sites should examine their potential to automate more functions that are currently being done manually, says **Judy Capko**, founder of Capko & Company of Thousand Oaks, CA. Capko is a healthcare consultant, speaker, and author of "Secrets of the Best-Run Practices."

"After all, staffing is the highest expense for medical practices," Capko says. "Also, automation gives you tools to do more thorough investigation and reporting, as well as refining the quality of services and care you are able to provide."

Here is some additional expert advice on how to weather the economic storm:

• **Focus on your CR mission:** Even in the best economic times, clinical trials are not a big money generator, Springer points out.

The goal is to conduct clinical research as part of the institution's mission to benefit both patients and science, he says.

"It's something that is mission-based, and it's the right thing to do for our patients and for their care," he says. "One of the things that happens is when you make money on one study, you use it on another study."

Clinical research sites need to keep this mind and make their economic goal one of balancing their more altruistic research work, including investigator-initiated trials with their better funded work for pharmaceutical and biotechnology companies.

"It's very important to us as an institution to have investigator-initiated studies, which utilize unique scientific strengths of our center and bring

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the benefit of this science to our patient population," Springer says. "But from a financial perspective, we try to run as close to breaking even as we can."

• **Cut costs where it's possible:** One way to do this is to look at the study staff, clinical trial team, and make sure the team is right-sized, Springer suggests.

"Make sure people are in the appropriate roles, and then you can do things efficiently," he says. "Figure out how to reduce your costs and improve quality."

The key is to right-size staff by making certain every employee is contributing to the site's quality performance, and that is only possible when the best performers are hired. *(See story on hiring high-performing staff, p. 88.)*

For instance, in the cancer research realm, sites will have CR staff that are more specialized in both clinical research and regulatory roles. Some work task division is necessary to keep the office running optimally.

"In my view, having a cancer nurse fill out regulatory forms is not a good use of nursing time," Springer says.

"I think you should apply the same business principles of any medical facility," Capko suggests. "Carefully monitor revenue against the cost of doing business and run a lean machine by eliminating waste, duplication, errors, and steps that do not provide an added-value to the patient or staff."

Many large academic research institutions have been cutting costs across the board by withholding pay raises, freezing benefit contributions, and shifting more health care costs to employees.

Clinical trial sites within these organizations will be impacted by these cost-cutting measures. They'll need to pay more attention to the staffing needs they can control, including putting more effort into hiring and retaining people who will be able to work in a high productivity, high quality environment, North says.

"During these economic times you might not be able to use an outside recruiter, whereas at one time we could afford it," she says.

• **Right-size the study portfolio:** "There are a number of studies and discussions of studies that don't accrue," Springer says. "You don't want to have hundreds of open studies that don't accrue and don't bring value to patients or the agency."

So CR sites should try to reduce their open studies to the ones they really need and will be able to meet enrollment goals.

"There are ways to make these more efficient, including using central IRBs and academic-cooperative groups, which have less of a burden and can be done with more studies and sites," Springer says. "Try to get rid of studies that don't accrue."

It's more difficult to small CR sites to right-size their portfolio, although they still can be cautious when selecting studies.

"My existing clients are putting more effort into examining potential studies to get involved with, and if it is a solo physician there may be challenges with recruitment," Capko notes.

All sites will need to identify creative ways to boost enrollment in slow-performing studies.

"For example, if you have studies and relationships with other centers and affiliates, you might be able to use that to boost the number of patients coming in for studies," Springer says. "Or, you could even share staffing costs."

There are examples of businesses that succeeded at increasing their business capacity when others were cutting back, including Southwest Airlines, which added flights while other airlines cut them, Springer says.

"For a while they were the only airline making money," he adds. "They're an example of taking advantage of a unique opportunity."

Some large cancer research institutions are following this strategy and are expanding despite the current economic issues.

"They're continuing to keep the mission going, extending their brand for what the center might do, accruing patients and getting novel collaborations and strategies, finding new funding mechanisms, foundations, and other support," Springer says. ■

In lean times, staffing decisions are crucial

Make lemonade out of economic lemons

Clinical research sites have a greater need than ever to find precisely the right people for the clinical trial coordinator and other research jobs. The continued economic downturn has resulted in research institutions cutting staff to the bare minimum, which means that every working hour has to count.

On the positive side, there have been some new opportunities for finding the best employees, says **Brian C. Springer**, MHA, executive vice president of Roswell Park Cancer Institute in Buffalo, NY.

"Pharmaceutical companies have been losing

positions too, dealing with the economy," Springer says. "This often can be a gain to the academic institution because it means there are a lot of really talented people out in the workforce who need jobs."

Often investigators need exactly the sort of experience and talent that can be found in pharmaceutical companies.

"For example, Washington University in St. Louis had job fairs for people coming from pharma who needed jobs," Springer says. "These forums brought together faculty and leaders with people displaced from pharma."

The pharmaceutical company's loss was the research institution's gain, he adds.

Research sites have higher expectations for their study coordinators now. The job is more difficult as subject enrollment has become challenging in the Internet era.

"Studies have been a lot harder to enroll, and patients are more educated than they were 15 years ago," says **Wanda Kay North,** PhD, MBA, RN, CCRC, CIM, manager of The Center for Clinical Research at St. Joseph's/Candler Health System in Savannah, GA. *(See story with tips on hiring good employees, at right.)*

"If you ask them to participate in a study they'll go on the web and get more information about the study, so it's not as easy to enroll people as it used to be," North explains. "We still have the crunch to enroll patients, but it's tougher now."

The other pressure is that staffing positions are reduced from the better economic days, and each person hired has to be more productive. North has had as many as six coordinators, but now has three coordinators on staff.

"You struggle," she says. "One thing I've realized over the years is that not everyone has what it takes to be a coordinator; it takes a special person."

Another strategy for finding high performance research staff is to look carefully from within an organization.

"Research organizations might be restructuring their offices, which sometimes gives us an opportunity find employees looking for different positions," Springer says. "From a human resources perspective, you win when you hire from within, and you do that less expensively than when you hire someone new."

Clinical research sites also need to be cognizant of making the best use of investigators' time.

"We try to facilitate research with our investigators so they can be as effective and efficient as possible," Springer says.

Another way research sites can make good use of staff time is through centralization. Not all research organizations have centralized CR services, but when these are available, they often work well.

"Instead of each investigator having their two data people and two clinical research nurses, it might be better to have a shared resource for some clinical trial services," Springer suggests.

"By having a shared resource we can be effective and fill people's time with work, and if there are changes in the workload that are associated with the study, and one investigator gets busy or busier, then we can allocate people to that task without having to hire additional people," he explains. "It's like the idea behind modular lab space."

Having centralized CR services provides a CR site with a group of skilled, hard-working people in clinical trials who are able to work on different studies as the workload changes, he adds.

Centralized services can produce higher quality and more efficiency, and it raises the bar on expectations.

"Some of the economic pressure can be good in helping us get to a more efficient model where we close studies that are not performing and give greater scrutiny to new studies coming in so that we're more selective," Springer says. ■

Tips on finding, hiring the best research staff

Ask for input from existing staff

Finding qualified and high-performing clinical trial workers who can work harder under more challenging circumstances takes patience and time.

Managers need to identify people who can work efficiently while under stress and fit in well with the clinical trial site's existing team, says **Wanda Kay North**, PhD, MBA, RN, CCRC, CIM, manager of The Center for Clinical Research at St. Joseph's/Candler Health System in Savannah, GA.

North offers this advice on how to find and attract the best qualified people for work at research sites:

• **Involve staff in decisions about potential employees:** "I've involved the team in the hiring process, which hopefully makes them feel like their input is important in hiring someone," North says. "When we interview, we make sure the staff has time with that candidate."

When coordinators talk among themselves, they

can go into the nuts and bolts details of the daily work and find out in a coordinator-to-coordinator conversation about any issues the job candidate has had on the job, she notes.

Current employees can also help market the position to potential hires by discussing positive attributes of the job.

"They can talk about the support they get from their manager and administrative staff," she adds.

After the research team meets with a job candidate, North would meet with each person individually to learn what he or she thought of the person.

"I'd like to see if they identified any issues and what they gained from spending time with the person," she says. "We're all different and focused on different things, so there might be an area that they've identified as important, and they want to get feedback from the candidate about this subject."

Also, North looks for trends in her staff's comments. I more than one person pointed out a shortcoming in the interviewee, then it would make her stop, go back, and find a way to speak with the job candidate again to see if this really is a problem.

"There have been times when an employee will come back and say, 'I don't think this person is going to work out, and this is why,'" North says. "If they have valid points they've identified, then I wouldn't hire the person."

• **Thoroughly check potential employees' records:** "If I hire someone with previous coordinator experience, I get a list of studies they've done, the number of patients they've enrolled, and what their enrollment goal was," North says. "I want to see if this person was good at identifying patients and enrolling patients in the study."

If a coordinator had enrolled only one or two patients for a study when the goal was 20-25, then that suggests the study was either very difficult to enroll or there are other issues going on, she explains.

"Everyone wants to find someone who is a go-getter and good at beating the bushes in finding patients for studies," North says.

"I've learned to check not just references, but their educational background," she says.

Also, North asks for a variety of references, including one from a monitor that has worked with the job candidate and a personal reference.

"Sometimes a personal reference has said something that makes me think I would not want to hire this person," North says.

Most people are leery about saying anything negative when they're asked for a reference, but occasionally someone will be candid about the job candidate's shortcomings.

Sometimes a job candidate will appear to be the ideal employee for a position, but issues will arise after they're hired, so it's good to have a short trial period.

"Within 90 days you can pick up on any issues," North says. ■

Leadership styles impact staff retention, morale

Reduce micro-managing; give more independence

Clinical trial managers have to toe the line between asking more of their staff, which might be greatly reduced during the continued economic downturn, and retaining employees and maintaining morale.

It's not easy to do, notes **Wanda Kay North**, PhD, MBA, RN, CCRC, CIM, manager of The Center for Clinical Research at St. Joseph's/Candler Health System in Savannah, GA.

"I had some experience managing people in my Air Force military career," North says. "But management is a little different on the civilian side. People can't just quit, and they can't say, 'I'm not going to do this.'"

North has learned how to manage clinical research staff over the past 13 years, after spending a few years working as a study coordinator. Her staff nominated her repeatedly for the St. Joseph's/Candler's Leintz Award for her compassion, care, drive for quality, and willingness to help others, and she won the award two years ago.

Here are North's suggestions for how to retain good employees and keep them content with their jobs:

1. Give employees some independence.

"You really need to be able to give some independence to your staff and trust them to know how to get things done," North says.

Managers might be tempted to take back that independence after one bad experience, but they should avoid this impulse, she adds.

"For me the biggest challenge has been to not just trust the staff but to make sure they know I trust them and know they're doing the best they can do," North says. "You do this by giving staff flexibility and independence where you trust they

know what they need to do and will go out and do it."

2. Avoid micromanaging.

Clinical research managers experience considerable stress from having tighter budgets, deadlines, and high performance pressure. But these factors do not justify micromanaging employees.

The manager who micromanages risks hurting staff morale and losing key people.

"Sometimes it's difficult to explain to study coordinators that they have to enroll subjects if they're going to keep their jobs," North says. "It's a fine line between how to push staff and how much to have your thumb on what's going on."

North has struggled with the impulse to micromanage, but she's forced herself to pullback and trust her staff.

"If I hire good people I have to trust them to do their jobs," she says. "The more you pressure staff, the less likely they'll stick around."

3. Respect employees' concerns over certain studies.

Study coordinators need to develop a rapport with subjects, and this often translates into an empathy that can lead coordinators to develop strong feelings about particular studies.

"I've had a coordinator or two who were assigned to a study, and they'd say, 'I am not sure this is a study I'd put a relative in,'" North says. "That made me stop and look at the protocol and make sure I wasn't missing anything."

CR managers can improve staff retention if they help coordinators to take a critical look at proposed protocols to see if these are studies the site might want to do.

"Have them analyze or evaluate them to see what their opinion is about a study you might bring in," North suggests. ■

Managing CT offices: delegate and train

Provide strong investigator oversight

Regulatory authorities in both the United States and Canada have been focusing on investigator oversight, an area in which clinical trial sites could have serious issues if their documentation is lacking.

"Investigator oversight is a focus of both the FDA [Food and Drug Administration] and Health Canada," says **Jacqueline Busheikin**, RN, CCRP, president of JANA Research Corporation in Calgary, Alberta, Canada. JANA Research is an independent clinical research consulting/monitoring organization.

"What I've done is go in and look at the documentation and processes at the site to see if it's possible to assess investigator oversight," Busheikin says. "In some cases, the problem is not that investigators are not overseeing trials, but that documentation is not there to show they're doing so."

Busheikin offers this advice on how clinical trial sites can improve their management and documentation of investigator oversight and other issues:

• **Delegation and training:** "One of the biggest issues is investigator delegation and training," Busheikin says. "Investigators at times delegate too much responsibility to other team members, particularly with their team members not being qualified to conduct those processes."

Also, sites that provide training might not document it clearly.

"That's a major issue, and you have people doing things they do not appear to be qualified to do," Busheikin says.

For example, a study coordinator who has an engineering educational background and who has had no or limited clinical research training might be expected to take a subject's blood pressure.

"That person is collecting medical information without the appropriate qualification or training in how to do it," Busheikin says.

Another example might be a small CR site in which an office manager or assistant is moved into a study coordinator position and is dispensing medications, despite the person's lack of a medical background, she adds.

"Those are the kinds of things that regulators are looking at," she says. "Research sites need to be aware of the requirements, qualifications, and training needed for particular procedures."

Research sites also need to be more familiar with the actual protocol and the procedures that will be required.

"Be cognizant of what qualifications are required for those procedures and be familiar with your staff so you'll know what employees are trained to do and whether they need support training," Busheikin says. "That's a big issue in terms of sending experienced staff to training courses, providing continuing education."

Clinical research sites need to ensure that their staffs are qualified to conduct all necessary procedures, and if they should document all training

employees receive, she adds.

• **Investigator oversight:** "Investigators need to be more aware of what the concept of oversight is so they are actually looking at more aspects and details of a research protocol and conduct of a research study," Busheikin says.

The key is to practice and document, she adds.

"Pay more attention to ensuring all patients are eligible in all aspects of a trial and that all procedures are done when they're supposed to be done for a protocol," Busheikin says. "Document what you're doing more robustly and make it clear you're participating more actively in a trial."

One solution might be to use checklists when documenting activity, but Busheikin advises against relying solely on these.

"Good documentation practices include narrative, as well as checklists," she says.

"People have to be cautious because we have a tendency to use checklists without checking them," she says. "They won't meet all the requirements of good documentation, so sites need to develop processes that will ensure that they are aware of all aspects of what needs to be done and then document these more fully."

Another strategy is to develop worksheets for study protocols. These can detail every procedure and the level of oversight necessary for each.

• **Documentation narrative:** A documentation best practice is to provide a narrative.

"Documentation for the conduct of a study needs to tell a story," Busheikin says. "In many cases, just answering 'yes' or 'no' doesn't give us information, just an outline."

There should be some background to support the information that's given, she adds.

"The purpose is not to recreate data that is collected but to recreate the environment and scenario," she explains. "There should be some context, and this sometimes requires a narrative and not just a checkbox."

The investigator or study coordinator should add information about how the procedure was conducted and why it was done a certain way, when it was done, and who did it, Busheikin says.

If a site has electronic documentation, then the electronic form could include a prompt that requests a narrative instead of just listing 'yes' and 'no' questions.

"A lot of times information is provided by pharmaceutical or device sponsors so tools are provided by the sponsor," she says. "This is fine in the sense that the tools should ensure that all information that needs to be collected for the trial is collected."

But investigators should keep in mind that the sponsor is only interested in a portion of data investigators collect for a trial, and sites are interested in broader information, including how well an individual study subject is doing in the holistic sense, Busheikin says.

"So a lot of times the site isn't collecting narrative information because they use the information the sponsor is using, and they document less fully than they need to be doing," she adds. "There's more emphasis now placed on the requirement for documentation to confirm that a procedure was done in the way the protocol described, and that it's in the right order, at the correct time, and all parts of the documentation need to be reported."

• **Standard operating procedures (SOPs):** Documentation issues can be resolved with good preparation, and that includes having an SOP that outlines what research employees do in a particular domain.

The SOPs can also list how a site will document its activities and which data collection tools it will use, Busheikin says.

Staff should be trained how to use the data collection tools properly, and this training also could be documented.

• **Checks and balances:** Clinical research sites can develop their own quality assurance practices by developing tools and systems for assessing quality and identifying errors or inconsistencies, Busheikin suggests.

"Have some quality checks during the study," she adds. "Periodically, someone should ensure everyone is doing what they need to do."

Quality checks can be based on regulatory requirements and good clinical practice guidelines. The person conducting the quality check should understand what exactly is required in terms of documentation, she says.

Studies with pharmaceutical sponsors will have a monitor conducting this quality check, and most monitors do a good job of this, Busheikin says.

• **Adverse events:** Some studies still collect everything that would meet the criteria of an adverse event, even if the AE is not related to the study product.

"We have to have more clear definitions in the protocol about what will and will not be collected," Busheikin says. "Adverse events need to be defined, and sites should be familiar with the definitions and reporting requirements for their particular trial."

Also, investigators need to be the person evalu-

ating all adverse events with respect to their relationship with the drug or device being studied, she adds.

Problems arise when the study coordinator makes the determination and the investigator may or may not review that determination, but there's no documentation verifying the investigator's input, she says.

"This is something that needs more attention at research sites because it's considered a medical decision or assessment, and it needs to be completed by an investigator," Busheikin says.

Documentation of adverse events should include additional data, such as a description of the event and the severity of the event. The protocol will have pre-defined criteria for assessing that severity, she notes.

"If an investigator feels the event is related to the investigational product because that's the information that will be provided as safety information when the product is marketed, then it's the investigator's responsibility to make the assessment," Busheikin says. "The investigator should be familiar with the investigational product from the product brochure and make the assessment based on this knowledge." ■

COMPLIANCE CORNER

Audits show researcher IC errors occur often

A big one? Using incorrect IC form

Clinical trial sites frequently make mistakes when conducting the informed consent process with prospective study participants, a compliance expert says.

"One of the responsibilities of an IRB is to observe the consent process, and I conduct random and directed audits of the process," says **Wendy Lloyd**, LPN, CCRP, CIP, regulatory affairs and compliance specialist, Vanderbilt University Medical Center, Nashville, TN.

When Lloyd finds a trend in informed consent mistakes, she addresses it by developing an education session for research staff.

"I offer to come directly to the department that's having the problem and tailor education to that department and study," she says.

Since informed consent is an area in which there were problems across departments, she developed a training series that focused informed consent.

The problems ranged from documentation to process. *(See table on common informed consent mistakes, p. 93.)*

CR investigators and managers who wish to prevent having poor audit findings involving informed consent, could take these steps to prevent problems:

• Understand what auditors or monitors will look for in the IC process:

The U.S. Food and Drug Administration (FDA) will send out warning letters when informed consent forms are incomplete, such as lacking documentation of the training and qualification of key study personnel who are conducting the IC process, Lloyd says.

"This is a huge issue with the FDA," she adds.

Both internal and outside auditors or monitors will look specifically at a site's documentation of the informed consent process and the forms themselves, focusing on these elements, Lloyd says:

— Does the consent document include all necessary elements?

— Does the document reflect and comply with the protocol?

— Has the IRB stamped its approval, and has the sponsor approved the document?

— Is the written form legible and understandable?

— Did the subject sign and ate the form prior to engaging in study screening procedures?

— Does the research site have a written policy for obtaining consent?

— Are there medical records documentation of the consenting process?

— Has the CR site implemented changes in the protocol only after receiving IRB approval, and was this done in a timely manner?

— Is the correct version of the protocol and consent form being used?

"You need to document completely and thoroughly the informed consent interactions," Lloyd says. "It's ongoing throughout the study."

• Audit your own informed consent documents.

"I encourage research sites to randomly audit their own consent documents and documentation," Lloyd says. "Also, it's a huge help for these sites to monitor FDA warning letters and OHRP determination letters."

By becoming familiar with the regulations, state laws, institutional, and IRB policies, creating SOPs, staying organized, and requesting department-spe-

Compliance specialist finds these common informed consent errors

Clinical trial sites often make similar mistakes when conducting informed consent with study participants.

Wendy Lloyd, LPN, CCRP, CIP, a regulatory affairs and compliance specialist at Vanderbilt University Medical Center in Nashville, TN, conducts audits of research sites and has found these common errors:

- Sites use expired consent documents.
- Consent documents are used that have not been approved by the IRB.
- The site has left off the names of key study personnel who will be consenting subjects.
- The person consenting the subject did not sign the form.
- Principal investigators have not maintained consent documents for the amount of time stated in the protocol.
- A research site cannot locate a consent document, or the subject was not consented.
- There are incomplete questions or sections in the informed consent document.
- Subjects were enrolled for the study when they did not meet the inclusion/exclusion criteria.
- The informed consent form listed an incorrect contact phone number.
- The informed consent document was not signed and dated at the time the consent was provided.
- The consent form used was for the wrong study.
- There are multiple consent documents for the same patients, and there is no explanation of how this occurred. ■

cific education are all good strategies for improving IC compliance, she adds.

"Verify your subjects' eligibility criteria prior to enrollment by having a second sign-off, a second person confirming eligibility," Lloyd suggests. "Verify that the consent is completely filled-out with no blanks."

Network with other research institutions to discuss the informed consent process because this is a good way to discover errors, she adds.

"You may not realize you're doing something wrong until someone else brings it up," she says.

Lloyd offers these ideas for what auditors and monitors look for in the informed consent document:

— Does the informed consent document include all necessary elements?

— Have option sections been addressed in the form?

— Are the IRB's approval and expiration dates listed?

-—Is the IC document used correct for this particular population?

— Is the most recently revised IC document?

— Is the signed document kept in one place?

"It's a best practice to keep all of your documentation in one place," Lloyd says.

Research sites also should get into the habit of including times with the dates when subjects sign the informed consent form. This is important because it can prevent findings that the subject began trial screening activity prior to fully consenting to the study.

For instance, the study coordinator or investigator should write in notes the time and date the consent form was signed because auditors might find a problem if the date of the signature and date of the first screening procedure are the same, Lloyd says.

By placing the time along with the date, the CR site can prove that the subject signed the form in the morning and did not start his or her first screening procedure until some hours after the informed consent process was complete, she adds. ■

CR INDUSTRY NEWS

New SACHRP members announced

The Office for Human Research Protections announced in late June, 2011, the selection of four new members of the Secretary's Advisory Committee for Human Research Protections (SACHRP). They were scheduled to be sworn in at the upcoming July 19-20 meeting.

The new members include the following:

• Albert J. Allen, MD, PhD, senior medical fellow, bioethics & pediatric capabilities, global medical affairs and development, Development Center of Excellence at Eli Lilly & Co;

• Gary L. Chadwick, PharmD, MPH, CIP, associate provost and director, office for human subject protection, University of Rochester;

• Susan Krivacic, MPAff, principal and consultant, PBG Consulting LLC;

• Suzanne M. Rivera, PhD, MSW, associate vice president for research, Case Western Reserve University;

OHRP will solicit additional nominees in early 2012. For further information on SACHRP, visit the website: http://www.hhs.gov/ohrp/sachrp/index.html. ■

OHRP answers CR sites' questions about FWA

The Office for Human Research Protections (OHRP) has posted on its website a revised set of frequently asked questions and answers (FAQs) on the assurance process that can be accessed at: http://answers.hhs.gov/ohrp/categories/1563.

These FAQs include information on recent changes in the Federalwide Assurance (FWA) form and Terms of Assurance, which have been approved by the Office of Management and Budget (OMB). On June 21, OHRP sent out a list serve notification announcing the availability of the OMB-approved revised FWA form and Terms. That notification lists the key changes in the form and terms and can be accessed at: http://www.hhs.gov/ohrp/newsroom/announcements/2011.html#20110620

Here is a sample of the FAQs developed by OHRP:

• What assurance of compliance process for human subject protection is accepted by the Office for Human Research Protections (OHRP) and other Federal agencies?

The Health and Human Service (HHS) human subject protection regulations and policies require that any institution engaged in non-exempt human subjects research conducted or supported by HHS must submit a written assurance of compliance to OHRP. The Federalwide Assurance (FWA) is the only type of assurance of compliance accepted and approved by OHRP. FWAs also are approved by the Office for Human Research Protections (OHRP) for federalwide use, which means that other federal departments and agencies that have adopted the Federal Policy for the Protection of Human Subjects (also known as the Common Rule) may rely on the FWA for the research that they conduct or support. Institutions engaging in research conducted or supported by non-HHS federal departments or agencies should consult with the sponsoring department or agency for guidance regarding whether the FWA is appropriate for the research in question.

• What is an assurance of compliance with human subject protection regulations?

An assurance of compliance is a written document submitted by an institution (not an Institutional Review Board) that is engaged in non-exempt human subjects research conducted or supported by HHS. Through the assurance of compliance, an institution commits to HHS that it will comply with the requirements set forth in the regulations for the protection of human subjects at 45 CFR part 46. The Federalwide Assurance is the only type of assurance of compliance accepted and approved by OHRP.

• When does a research institution need to be covered by an assurance of compliance with human subjects research protections?

All institutions engaged in human subjects research that is not exempt from the regulations, and is conducted or supported by any HHS agency must be covered by an Office for Human Research Protections-approved assurance of compliance (http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html). The Federalwide Assurance (FWA) is the only type of assurance of compliance accepted and approved by OHRP.

An institution may extend its FWA to cover a collaborating individual investigator under certain conditions using the sample Individual Investigator Agreement or a comparable agreement developed by the institution.

• When is an institution considered to be "engaged in research"?

In general, an institution is considered to be engaged in human subjects research when its employees or agents:

(1) obtain data about living individuals for research purposes through intervention or interaction with them;

(2) obtain individually identifiable private information for research purposes (45 CFR 46.102(d),(f)) http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.102; or

(3) obtain the informed consent of human subjects.

Employees and agents, including students, are

individuals performing institutionally designated activities and acting on behalf of the institution or exercising institutional authority or responsibility.

In general, an institution is considered to be engaged in human subjects research whenever it receives a direct HHS award to support such research, even if all of the human subjects activities will be performed by agents or employees of another institution. In general, simply informing potential subjects about a research study is not considered engagement in research. Also, providing written information about a research study, including how to contact the investigators for information and enrollment, and seeking and obtaining prospective subjects' permission for investigators to contact them are not considered engagement in research. However, obtaining informed consent from a research participant is considered engagement in research. [For details, please see OHRP guidance on this topic at: http://www.hhs.gov/ohrp/policy/engage08.html, specifically, Section (B)(4).]

• What is a Federalwide Assurance (FWA)?

The Federalwide Assurance (FWA) is the only type of assurance of compliance accepted and approved by OHRP for institutions engaged in non-exempt human subjects research conducted or supported by HHS. Under an FWA, an institution commits to HHS that it will comply with the requirements set forth in 45 CFR part 46, as well as the Terms of Assurance.

FWAs also are approved by OHRP for federalwide use, which means that other federal departments and agencies that have adopted the Federal Policy for the Protection of Human Subjects (also known as the Common Rule) may rely on the FWA for the research that they conduct or support. Institutions engaging in research conducted or supported by non-HHS federal departments or agencies should consult with the sponsoring department or agency for guidance regarding whether the FWA is appropriate for the research in question.

There is a single version of the FWA and the Terms of Assurance for domestic (U.S.) institutions and international (non-U.S.) institutions.

• What research does the Federalwide Assurance (FWA) cover?

The FWA covers all non-exempt human subjects research at the submitting institution that is HHS-conducted or -supported or funded by any other federal department or agency that has adopted the Common Rule and relies upon the FWA. It is not project specific. Domestic institutions may voluntarily extend their FWA to cover all human subjects research at the submitting institution regardless of the source of support for the particular research activity.

• What time period does the Federalwide Assurance (FWA) cover and when does it have to be updated?

The Federalwide Assurance (FWA) is effective for 5 years and must be renewed every 5 years, even if no changes have occurred, in order to maintain an active FWA. The institution must update its FWA within 90 days after changes occur regarding the legal name of the institution, the Human Protections Administrator, or the Signatory Official. Any renewal or update that is submitted electronically, and approved by OHRP, begins a new 5-year effective period. ■

CNE/CME OBJECTIVES & INSTRUCTIONS

The CNE/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.

To earn credit for this activity, please follow these instructions.

1. Read and study the activity, using the provided references for further research.
2. Log on to www.cmecity.com to take a post-test; tests can be taken after each issue or collectively at the end of the semester. First-time users will have to register on the site using the 8-digit subscriber number printed on their mailing label, invoice or renewal notice.
3. Pass the online tests with a score of 100%; you will be allowed to answer the questions as many times as needed to achieve a score of 100%.
4. After successfully completing the last test of the semester, your browser will be automatically directed to the activity evaluation form, which you will submit online.
5. Once the completed evaluation is received, a credit letter will be e-mailed to you instantly. ■

COMING IN FUTURE MONTHS

■ Create an efficiency team or process to improve site's operations and quality

■ Make compliance a top-down focus

■ Improve Medicare reimbursement processes for trials

■ Develop best practices for electronic solutions

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CNE/CME QUESTIONS

29. Which of the following is a list of strategies clinical research sites might use to improve their financial picture?
A. Right-size staff and right-size the study portfolio
B. Use outside clinical research vendors and hire head-hunters to find qualified staff
C. None of the above
D. All of the above

30. True or False: Investigators at times delegate too much responsibility to other team members, particularly with their team members not being qualified to conduct those processes.
A. True
B. False

3.1 Which of the following questions should sites ask about their informed consent document to ensure compliance with regulations?
A. Does the informed consent document include all necessary elements?
B. Are the IRB's approval and expiration dates listed?
C. Is the IC document used correct for this particular population?
D. All of the above

32. According to the Office for Human Research Protections's guidance on Federalwide Assurance, when is an institution considered to be engaged in research?
A. When its employees or agents obtain data about living individuals for research purposes through intervention or interaction with them
B. When its employees or agents obtain individually identifiable private information for research purposes
C. When its employees or agents obtain the informed consent of human subjects
D. All of the above