CLINICAL TRIALS
ADMINISTRATOR
An essential resource for managers of clinical trials

Note: New CNE procedures. See p. 83 for details.

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AHC Media

What CR sites need now is Financial Management 101

Better terms, collections & budgets

It's difficult to imagine another industry that would tolerate six- to 18-month lag times on payments for services or products. Yet it has been a tradition in the clinical research (CR) industry.

This budding trend is part of a bigger picture in which CR sites are becoming aware that better financial management will be crucial to their survival in an increasingly difficult clinical trial industry.

Some CR leaders are forming best practices that include asking for, and often receiving, 25-30 day payment cycles. They're also managing their accounts receivables more actively, and are making other changes that result in higher productivity and better cash flow.

The prolonged recessionary climate has been damaging for CR sites, and each year a number of them close because of their inability to manage their finances. One of the problems is that they have to make payroll every two weeks while sponsors might make them wait months for reimbursement for their work, experts say.

"I suspect a lot of businesses are suffering through that slow-payment process," says **Bobbi Tafara,** CCRC, director and owner of Suncoast Clinical Research in New Port Richey, FL.

Suncoast Clinical Research has addressed this issue in the past couple of years by asking sponsors for 30-day payments in contracts, Tafara says.

"I've heard of a number of sites that have closed their doors, and, sadly, a number of people couldn't ride out the storm," she says. "But we've been around since 1988, and we apply conservative principles to our financial management, and I think that's paid off."

The most recent principle has been to ask for better payment terms while showing sponsors what the site can deliver. This is a trend that's beginning to catch on with other CR sites too.

Aspen Clinical Research in Orem, CO, began to ask for 25-30 day payments from sponsors at the beginning of 2010, says **Jon Ward**, BSc, CIPN, CCRC, chief executive officer of Aspen Clinical Research.

Also, the research organization has asked sponsors to make pass-through payments on a monthly basis instead of quarterly, he adds.

"Pass-through invoices like advertising and imaging services and pharmacy preparation are paid monthly, which means within 45 days of the actual event occurring," Ward explains. "If we did an MRI on the first of

this month then we want it paid by the 15th of the following month."

The switch from quarterly payments to monthly payments has taken some time, but it progresses with each successful study, Ward says.

For instance, Aspen Clinical Research's first contract with a sponsor might be set at the quarterly payment cycle. But once the CR organization proves that it can deliver studies on time and produce quality data, Ward will ask for monthly payment cycles for any future studies.

"We build a relationship and build up rapport," Ward says. "Too many people are afraid to ask for it."

Sponsors and CR leaders should view the current three to six-month payment cycle as a major problem for the industry, he says.

"The more research sites lack payments, the more stress it puts on a site," Ward says. "And the more a site stresses about payments and bills, the more it distracts from their overall ability to collect data."

Tafara has helped build momentum for monthly payment cycles when she meets with industry leaders at CR conferences and courses. It takes CR site leaders to push the pharmaceutical chief executive officers and the industry toward this trend, she notes.

"People in the industry and who have a good reputation can say, 'Look here, these are my results; I do good work and I want something in return for that,'" she explains. "That's a push that's going on and it seems to be working."

CR sites also should ask for better reimbursement for study procedures, and they can only do this if they have a thorough and accurate budgeting process, says **Steven Ziemba**, MS, MBA, PhD-candidate, director of clinical research at Phoebe Putney Memorial Hospital in Albany, GA.

Researchers at large institutions need accurate budgets for both the site's financial well-being and also to justify any requests they make for hiring new staff, Ziemba notes.

"Let's say your site is understaffed, and you're not necessarily tracking revenue coming in, or you're not negotiating an adequate amount to cover your costs and other expenses," he explains. "When you come back to the administration to say you really need a data manager or research nurse, you have to demonstrate that revenue increase."

If a CR director cannot demonstrate that the site has enough business and revenue to justify the new staff position, then it will be difficult to convince the administration that the need really is there, he adds. *(See Ziemba's tips for developing an accurate budget and chargemaster, p. 76.)*

"A research administrator should be familiar with exactly how much you should be charging on an hourly basis for your staff members," Ziemba says.

Tafara and Ward suggest these additional ways that CR sites can improve their financial management and succeed even during difficult economic times:

- **Be proactive with accounts receivables:** "My

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Editor: **Melinda Young**.
Executive Editor: **Michael Harris**,
(404) 262-5443 (michael.harris@ahcmedia.com).
Production Editor: **Kristen Ramsey**.

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EDITORIAL QUESTIONS

Questions or comments? Call Michael Harris at (404) 262-5443.

key point is, 'Why aren't these guys actually paying?" Ward says.

Often the hold-up is an oversight, and the sponsor simply needs a reminder.

This is why Aspen Clinical Research sends out routine invoices regardless of the sponsor's preference.

"Most monitors and CROs [clinical research organizations] say, 'Don't send me invoices; these forms are sent out automatically, so we can't do anything about it,'" Ward says.

But this means that payment could be delayed even when everything has been cleared and accepted by the monitor.

"So we send out invoices automatically every two weeks, and we include all the supporting data," Ward explains. "If the invoice is for advertising, we send out details from the media company, the IRB's approval of the ads, and the monitor's email that said we should go ahead with the ad."

Another strategy is to move away from having contracts based on what was monitored and to instead have them based on data entered and approved without query, Ward suggests.

"If there are no conflicts, then we submit this for payment," he adds.

Research sites should install a good clinical trial management system, selecting one that is adaptable to their own business models, Tafara suggests.

"The system we're using now is more supportive and user-friendly of our invoicing process," she says. "When we were smaller we could rely on an individual's follow-up and memory, but you can't do that when your site gets bigger and your receivables are larger."

Research organizations should pay attention to their contracts' fine print, especially if they do not send out invoices routinely.

Some sponsors will send payments automatically, but others might hold off until they receive an invoice, and a research site might not realize that is the case, Tafara says.

Electronic clinical trial management systems also should include reminders about overdue invoices. And sites should track their own follow-through on payments to see if they are letting money fall through the cracks.

"Be extra diligent and review what you do periodically," she says. "A lot of companies run reports and never look at them."

• **Know your costs and true budget:** "When we first receive a contract, we have an employee who compares what is offered with what our metrics are for the different services," Tafara says. "If a sponsor is offering 50% of what we'd typically bill for that service, then we have to provide justification for why our charge is higher."

Every clinical trial organization should build up its own metrics to identify the site's profit margin, Tafara says.

This retrospective review of costs should grow as the site grows.

"It's a variable business, and probably every month a study comes along that has a new process or service in it," Tafara says. "You do your work and find out what it costs and negotiate for that fee and add it to your metrics."

The key is to be flexible and grow, she adds.

• **Hone negotiation skills:** CR sites can do a great job tracking and collecting payments, but if their contracts are structured in a way that costs them money with unrealistic timelines and expectations, then there's a problem, Ward says.

Contracts based on unrealistic timelines and expectations should be avoided.

"Negotiate for 25 to 30 day payments," Ward says.

Sites also should negotiate for administrative and start-up payments to help tide them over during the first long stretch before they enroll subjects and begin to bill for the visits, he says.

"The costs are there, so we have to have the start-up payments in place," Ward says. "Even if you are a phenomenal enroller, your payment easily could be five months after your first subject was enrolled."

The best strategy for negotiating better payment terms is to create value for your research site by meeting goals, he says.

"We typically under-promise and over-perform on all of our contracts," Ward says.

Research sites can make handshake deals with sponsors, in which they can demonstrate their commitment to a study by meeting enrollment and data collection goals in exchange for a promise to agree to a monthly payment schedule in the future, he says.

• **Ask subcontractors for better prices:** "Don't be afraid to ask," Tafara says. "When we outsource our radiology tests, we go to the radiology facility and ask them to accept the Medicare allowance rate."

Sometimes Tafara will ask a vendor to accept the Medicaid prices.

"We ask vendors, 'What is your best price?'" Tafara says. "I think most facilities accept that this is like a Medicare payment and that's all they're

going to get for the service."

Clinical research sites need to protect their bottom line by buying on bulk and paying attention to everything they outsource or buy, she says.

"You have to ask," she says. "There's no place to be shy or humble."

• **Operate more efficiently:** Clinical trial business often results in busy and slow periods. Many sites will reduce their staff when times are slow and add more employees when business picks up.

But this is not necessarily the most efficient way to operate since it's very costly to hire and train new employees, and sites lose valuable experience when they let go of existing professionals.

A better method is to cross-train staff and help employees build skills that could be useful in the lean times.

For example, Suncoast Clinical Research will shift clinical trial staff to recruitment work when there are fewer studies underway.

"If you don't have a lot of studies, then you can enroll more people into the studies you do have, Tafara says. "They could review charts in physicians' offices, make phone calls, and distribute fliers in the community."

Sponsors rarely tell sites to not enroll more subjects because a number of their sites will underenroll, she adds.

Shifting staff to new roles makes everyone happy, she notes.

"When they enroll more patients they can go back to seeing patients," Tafara says. "It's a win-win-win."

At Suncoast Clinical Research, each employee is trained in all study visit tasks so they can serve as back-ups when needed.

"Our coordinators know how to recruit, see patients, draw blood, enter data, and schedule appointments," she says. ■

Tips for a more useful, accurate CR budget

Make chargemaster, calculate complexity

The bottom line to better financial management of any clinical research (CR) site is the budget. Better budgets lead to better negotiating, staffing, and contracts. So it's a great place to start a quality improvement project.

"A budget to me is taking your time, effort, and procedures and translating them into dollar amounts," says **Steven Ziemba,** MS, MBA, PhD-candidate, director of clinical research at Phoebe Putney Memorial Hospital in Albany, GA.

Ziemba outlines the process for determining the most accurate clinical research budget with these best practice tips:

• **Calculate your true productivity/labor costs.**

"Of all of the clinical research expenses, the biggest one is labor," Ziemba says. "The reason is that most of what you are doing on a study is collecting data, interacting with patients and physicians, and this involves labor and time."

The key is to know the best methods for calculating labor and other CR costs, and the best way rarely is the easiest way, Ziemba notes.

"It's not as easy as it sounds," he explains. "You don't just take the annual salary of a research nurse and divide it by 2000 or the number of working hours."

The calculations need to include productivity, which is the total compensation broken down into units of time that encompass actual working time, as well as vacation time, sick time, and benefits, including health insurance, disability insurance, retirement funding, and other items, he says.

"What I mean by productivity is you might have 2000 hours in a work year, but how many of those would be available for working?" Ziemba says. "You have to take into consideration vacation hours, deducting that from the 2000 hours, and other things."

Plus each employee's salary has 30% added onto it in benefits. So for an example, the total for salary and compensation might be $65,000 per year. Then this is divided by maybe 1400 actual productive work hours to come up with the formula that is used to calculate the per hour labor costs, he explains.

• **Determine how much time is spent on each study task.**

The next step is to calculate how many hours it takes to do each task that is performed during a clinical trial.

"You could do a time study as is done in other departments in a hospital," Ziemba says. "But for clinical research it's not that simple; for instance, with informed consent you have different amounts of time it takes to do it depending on the study and its level of complexity."

Plus each patient will vary in how long it takes to understand the study and complete the informed consent process, he adds.

It's possible to arrive at base numbers that can be adjusted from study-to-study, but it's not

always possible to create a standard number for research tasks, he says.

"I've seen estimates of two to three hours minimum for informed consent and up to four times as much as that," Ziemba says.

Another variable in conducting informed consent is the research nurse or coordinator who is conducting it. Some will take longer to reach the point of deciding the potential participant fully understands the study and what will be required of him or her, he adds.

• Estimate study complexity and include that in budget preparation formulas.

"Some articles in the literature can be used to estimate the complexity of a study," Ziemba says. "But I would urge in the use of these articles that you are careful of what you are reading because it's possible you might miss something that would impact the complexity, or there might be an issue that is unique to your site."

For instance, a particular research site might have limited staffing or other resource issues that impact complexity.

• Create a chargemaster that uses budget cost and unit calculations.

The chargemaster should include start-up cost information, including everything that needs to be done to get a study going, Ziemba says.

Each research site should know what it costs to keep a study running without any enrolled patients, and then they should factor that into their negotiations. Even though sponsors might consider certain administrative costs as the cost of doing business, they still should be calculated, he says.

"We will request a submission of safety reports, requesting money for that because it will take time to put them together," Ziemba says. "Also, you have to keep in mind to charge for IRB fees, if you're using an IRB."

As a CR director works on the chargemaster, it's a good strategy to meet with the billing department to see if they can help determine the cost of the study's procedures, such as a CT scan.

"That's a good place to start with your chargemaster, and it's a good place to go to on a regular basis when you want to update your chargemaster," Ziemba says.

The chargemaster essentially is an Excel spreadsheet that is broken into different sections and pages. One is for administrative costs, including IRB fees, start-up fees, and other departmental tasks, Ziemba explains.

"Other tabs cover radiology or hospital-based fees or cancer center fees," he adds. "Then you have your per visit items."

These are items that can be stored to be used across studies. They should be updated at least twice a year, although Ziemba makes changes each time he does a new budget.

The most time-consuming part of creating a chargemaster involves adding items particular to the protocol, Ziemba says.

"Go to the schedule of events and compare that to the budget," he suggests.

This can take anywhere from a day to a week, depending on the study's complexity, he adds.

• Use your budget/chargemaster when negotiating contracts.

Make time for negotiating and be sure the chargemaster is on the desk when negotiations take place, Ziemba advises.

"Try to make the time to actually do the negotiating," he says.

"You don't want to be in a situation where you're working on one thing and when the sponsor calls up to discuss the budget your mind is somewhere else and you don't have the chargemaster in front of you," he says. "I recommend that you say, 'Can we reschedule this for a better time?'"

The key is to not let sponsors speed up the negotiation process.

Both sides are trying to reach a satisfactory agreement, and the CR site needs to know its budget in order to negotiate a fair price for the study, Ziemba says. ■

Create tools to facilitate efficient documentation

Make your own site source documents

The site source documents sponsors send to clinical research sites often lack some important information the sites need in their efforts to comply with research rules and regulations. So a research organization in Memphis, TN, has created its own coordinator tools and source documents.

This improves its documentation and operational organization and allows for easier monitoring and auditing, says **Derita Bran**, RN, CCRC, manager of clinical trials operations at UT Medical Group Inc. of Memphis.

"We felt like we were good at doing what we needed to do," Bran notes. "But we felt it would

help with organization if we created a site checklist to document compliance with all ICH GCPs [good clinical practices]."

For example, Bran created a site source document that lists all the ICH GCPs for informed consent. It has the principal investigator, coordinator, or co-investigator mark "yes" or "no" for 15 different steps. *(See informed consent checklist box, p. 79.)*

"Sponsors' site source documents do not always cover everything you need," she says. "They might not show the principal investigator's oversight or documentation of ICH GCPs."

While it's time-consuming creating these checklists and templates, they save staff time during studies because they make it easier for coordinators to complete documentation. Also, the templates can be used to more quickly put together site visit checklists for studies, she adds.

"Our informed consent checklist is okay for all studies, but for specific study visits we'll need to change these for each protocol," Bran says.

UT Medical Group's research staff loves the idea of the checklist because it saves them time and hassle when compared with the old process of handwriting documentation notes, she says.

"At the beginning of a study it takes time to set these up, but the more someone creates them the less time it takes," she explains. "Depending on the protocol, it might take 30 minutes to a couple of hours to create the site source documents for all of the study visits."

Here is how Bran and site coordinators create the site source documents for each study:

• **Include all regulatory and other compliance standards:** The first step is to create templates that incorporate all of the regulatory documentation and process steps needed in clinical trials, including following the Food and Drug Administration (FDA) regulations and the International Conference on Harmonisation (ICH) /World Health Organization (WHO) Good Clinical Practice standards. The ICH guidelines are standards for the United States, the European Union (EU), Japan, Australia, Canada, and the Nordic countries.

"The ICH GCP standards are more detailed than FDA regulations, and they give more specific directions of what to follow," Bran says.

The differences can be subtle, but important in documentation.

For example, the FDA regulations say that research sites should give the subject a copy of the informed consent form while the ICH GCPs say sites should give subjects a signed copy of the informed consent form, Bran explains.

Research coordinators can draw from guidelines when creating templates for the site source documents. One that might prove useful is the FDA's 2009 information sheet on principal investigator responsibilities. Other sources include the research institution's standard operating procedures (SOPs).

• **Obtain input from research coordinators and anyone else who uses the documents:** Bran started this process by speaking with coordinators about key information needed in site source documents.

Bran explained the reasons why a research site needs its own site source documents and cannot always rely on the sponsor's material. And she obtained buy-in and trained coordinators how to create their own site source documents for each study.

Coordinators can pull site source documents from other studies, copy and paste the information, and then tweak these to fit the new protocol, Bran says.

• **Adapt templates to the sponsor's requirements:** Each site visit source documentation checklist is adapted to the protocol's site visit information. But research coordinators also can adapt the document to other information requested by the sponsor.

"If the sponsor gives us a checklist or worksheet and they want us to use their checklist, then we use ours in addition to theirs," she says.

"I had a sponsor several years ago who I sent our site source documentation to make sure they were okay with it," she adds. "The sponsor ended up asking if they could use our site source documentation for all 50 of their sites."

It's more common now for sponsors to have their own checklists and worksheets, so these can have additional information to add to the site's own site source documentation material, Bran says.

• **Keep checklist detailed and specific:** It's important that every single step is noted in the site source document because even the smallest detail could prove important later in during an audit.

For example, in a women's health study, participants might be required to have a urine test and pap smear, Bran says.

"The protocol stated that you perform the urine test before the pap smear," she explains.

The worksheet/site source documents reflected that timing nuance: "We put down that the urine test was performed before the pap smear, and we included a checklist that showed compliance," Bran says.

"We could have written down the times that the pap smear and urine test were performed, but it was easier to put it in a worksheet or checklist, and it helps us as a guideline to know what steps to take for that visit," she adds. ■

Reduce COI issues by focusing area attention

Big changes on COI rules are coming soon

Research coordinators and investigators sometimes fail to imagine all of the different types of institutional responsibilities that could be affected by a conflicts of interest (COI) policy.

A large academic medical center that conducts research could have separate COI policies and processes for its medical center and its research activities. But physician investigators would be subject to both sets of policies, says **Charlotte Talman,** MSN, MBA, director of the conflict of interest office in the office of the vice president for research at the University of Iowa in Iowa City, IA.

"Research is the one that's guided by federal regulations while the other processes are guided by whatever their internal policy is," Talman says.

The Food and Drug Administration (FDA) and the U.S. Department of Health and Human Services (HHS) have regulations pertaining to COI, and they have some different features, she notes.

"The more stringent one is HHS because they fund a lot of research through the National Institutes of Health," she adds. "That's what most investiga-

Here are site source document sample IC items

Every step is documented

The UT Medical Group Inc. of Memphis, TN, creates source documentation checklists for site visits, screening visits, and other clinical research activities. Here are some sample items included on the template for a screening visit that includes an informed consent process:

- All of the inclusion criteria have been met (Yes or No)
- None of the exclusion criteria have been met (Yes or No)
- The following person(s) were present for the informed consent process: (fill in the blank)
- The consent form/study was explained by: (fill in the blank)
- If the PI/sub/co-investigator was not present for the informed consent process, (fill in the blank) was available to answer questions
- Dr. (name) is aware the subject was enrolled in the study on (date)

And it includes these yes and no checklist items:

- The IC process was performed in a comfortable, quite, and private location
- The subject and/or LAR was given ample time to read the consent form
- Version (fill in blank) of the ICF was signed today before any study procedures were performed
- The subject and/or LAR was offered the opportunity to take the ICF home to discuss with others; the ICF was taken home
- The contents of the informed consent were discussed with the subject/LAR including the following nature of the study, randomization, risks/benefits, duration of participation, no penalty for not participating, side effects, procedures (designating which one(s) are for research purposes only)
- The subject and/or LAR was encouraged to ask questions regarding the study; Questions asked by the subject/LAR (fill in the blank)
- Methods other than discussion were utilized to explain the study; If so, list other methods (fill in the blank)
- All questions were answered to the subject/LAR's satisfaction and understanding
- Subject/ LAR voiced understanding
- Subject/LAR voluntarily agrees to participate in the clinical trial
- Subject verbalizes that he/she has read the informed consent form
- ICF signed prior to any study related procedures being formed; Date/time ICF was signed (date/time)
- Copy of the signed and dated ICF given to subject/LAR
- Was a witness utilized during the process? If so, explain (fill in the blank)

The form also contains room for comments, date of next scheduled visit, and signatures with dates by study team member completing form and the principal investigator. ■

tors adopt to cover all research at their university, and that's the policies we've had in place since 1995."

Research institutions like the University of Iowa now need to revisit and revamp these dusty COI policies since HHS has proposed some big changes in COI regulations, Talman says.

The proposed changes have had two comment periods so far, and substantial changes are expected to be made final sometime this summer.

One major proposed change would reduce the disclosure burden from a per study basis to an annual basis.

"They're moving from a per-project to annual disclosure, and the thresholds are lower," she says.

"That will help us dovetail with what our medical center has been doing for the past two years," Talman says. "At the beginning of the year, researchers would have a two-month period to disclose what their outside interests are, including intellectual property, and so on."

The research institution would need to evaluate that information based on what the researcher's study portfolio contains to look for conflicts of interest, she adds.

Talman worked on a committee on conflict of interest with the Association of Academic Medical Colleges. A number of organizations like AAMC have had suggestions for HHS about the proposed changes. *(See best practice suggestions for preparing for changes, below.)*

For example, one change would be that the NIH requires institutions to disclose any compensation from outside interests in excess of $5,000, which is half of the current $10,000 threshold, Talman says.

"We question the $5,000 threshold," she adds. "It seems arbitrary."

The proposed regulations would impact researchers who have an issued patent.

"Anyone who has an issued patent creates in the eyes of the federal government a financial interest related to research," Talman says. "Not a lot of those issued patents go on to be commercialized or licensed: 95% never get picked up to be commercialized and do not earn money for anyone, so why do they base this on issued patents?"

Instead it should be based on patents that are licensed, she adds.

Expert's suggestions for COI policy best practices

Proactive disclosure works well

Research institutions have conflicts of interest (COI) policies that likely will need to change when new regulations are rolled out from the U.S. Department of Health and Human Services (HHS).

As they prepare for these changes and increased regulatory burden there are some best practice strategies they could follow, suggests **Charlotte Talman**, MSN, MBA, director of the conflict of interest office in the office of the vice president for research at the University of Iowa in Iowa City, IA.

Here are some of Talman's suggestions:

• **Merge clinical care and research COI policies and procedures:** "We're merging our whole system at our medical center and our research system so that everyone only has to do one disclosure form per year," Talman says. "They have to update it if something changes, but it's one-stop shopping."

Talman and her counterparts at the institution's medical center are working together to write a web-based form that cover both side's COI policies and procedures.

"We have 7,000 to 8,000 disclosure forms a year that will come to us, and that's a lot," Talman says. "When I see that somebody has submitted a grant proposal seeking funding and I look at the list of names involved in that research, we have to either manually or automatically make sure there's a disclosure form on record for them."

An electronic and merged system will lessen the administrative burden, and the merged system will make the process far more efficient for clinician researchers.

"I don't want researchers to have two disclosures," Talman says. "I want to make it more efficient and user friendly because it's too confusing otherwise."

• **Address the perception of COI, as well as the actual conflicts:** "A negative perception of a conflict of interest can be just as damaging as if there were actual bias on the research," Talman says. "The name of the game is transparency."

Proactive disclosure is a good policy.

"When we manage what we view as a conflict of interest in research, our usual management plan is to tell everyone, including students who work in the lab, participants, readers of publications and presentations," Talman says. "Explain that you have a consulting agreement with a company that has some interest in the research results, and then they can make up their minds." ■

The question is whether HHS is correctly interpreting its COI goal of preventing the possibility of introducing bias in research based on a conflict of interest.

"If you have some technology that has been patented, and you're using that technology in your research then that could create bias in how you interpret the findings," Talman says. "You could introduce bias into your research because you slant the findings toward making your patent look more favorable."

Then if the patent is licensed, the investigator or research institution would receive revenue from it. But if it's not licensed, maybe it will suffice to disclose the conflict, she adds.

The proposed rules would increase the amount of information that research sites send to the NIH when they have a conflict of interest, Talman says.

"Currently we provide a minimal amount of information to them, but now it's hugely changed, and the amount has increased, putting a big burden on research institutions," she says. "This will require four times the amount of information we currently have to give them, and that's a real drain on institutions when everyone is hurting financially and we can't hire more staff."

Also, the proposed rules would require mandatory training on research COI every two years.

"That's a pretty big change," Talman says. "Every two years every person who has a key role in research must be up to date on their COI training."

Public disclosure of COI also takes on new meaning in the proposed rules.

"The other big change is that the information needs to be publicly available on the Internet and posted on the Web, so it's really public disclosure," Talman says. "Even posting information on the Internet puts a huge burden on institutions."

Research institutions will have to develop a system for posting the COI information, updating it, and providing context.

"You can't just add another web page, and we're not going to be funded to do that," Talman says. ■

Assess your QI program and adjust according

Education reflects audit findings

Through evaluation programs, a research institution can learn what works and what doesn't in its quality improvement efforts.

Many research organizations have quality improvement (QI) and auditing programs that conduct for-cause and/or not-for-cause audits of research projects. This checks and balance strategy works well for ensuring compliance in human subjects research. But it might not go far enough in improving overall institutional quality. For instance, who evaluates the QI or auditing program to make certain it is working as well as it should be working?

Winthrop University Hospital in Mineola, NY, started an audit program in 2004, focusing on the educational aspects of the program, says **Tina P. Berry,** CIP, IRB director.

"About a year ago, I thought we needed to evaluate the program and see how it's doing," she says.

Berry met with the QI coordinator and others in the research program to identify how the educational effort was working and to assess its results. They looked at trends found in the QI audits and how these were being addressed.

Among the issues discovered, Berry found that communication about QI issues could be improved between investigators and their staffs.

Another issue involved the QI coordinator's role and clinical trial staff's perception of that role. Too often people saw the QI audits as punitive rather than educational, she adds.

To counter this perception, research staff and investigators were invited to a 2.5-hour educational session with the QI coordinator. Later, the attendees of the session were assessed for their compliance with human subjects research guidelines. The research institution also holds monthly educational sessions.

Both QI audits and the educational sessions have focused on informed consent issues, which tend to be one of the biggest identified trends, Berry notes.

Sites sometimes fail to use the right informed consent form, and documentation is sloppy, she adds.

The monthly educational sessions are marketed through fliers and newsletters. They are not mandatory, but are well-attended, Berry says.

The 2010 series included sessions on a variety of topics, including the following:

- What is good clinical practice?
- How do you navigate the process of investigator-initiated projects?
- How does clinical research look like through the eyes of children?

• How do you write a research protocol for IRB approval?

• An overview of the use of biological specimens in human research.

The 2011 monthly workshop series agenda includes these topics:

• Overview of consenting — especially in non-English-speaking subjects

• Sample size and ethics

• Investigator-initiated studies: phase I, II, and III

• Internet research and electronic data security

• Women in research

• Grants and contracts

• How to write an IRB-approvable research protocol

• An overview of the use of biological specimens in human research — a discussion on the use of identifiable and unidentifiable samples

• Ethical considerations in human subjects research.

The courses are taught by experts. These include IRB members, research coordinators, department chairs, and others. Their disciplines are varied, ranging from biostatistician, research pharmacist, grants specialist, and physicians.

"Sometimes these topics have to be repeated," Berry says. "We collect information from all of our audits and compile this information along with quality information, and come up with the issues we need to focus on." ■

COMPLIANCE CORNER

IC tools help validate, discuss and document

Research site uses barcoding for informed consent

Large and state-of-the-art research organizations are proving that technological solutions can make every compliance effort more efficient and better documented. For example, barcoding moved from the grocery store to the hospital, and now it can be used to validate research participants and the informed consent process.

"By pushing documents to the Web, we've incorporated barcoding," says **Laury Finn,** CCRP, supervisor and research regulations specialist at the University of Texas M.D. (UTMD) Anderson Cancer Center in Houston, TX.

UTMD's online database with protocol documents includes informed consent forms. The informed consent process is well-organized to ensure compliance, based on the following three steps:

• **Validate/confirm: choose the correct subject and study;** determine possible eligibility; retrieve bar-coded informed consent.[1]

• **Discuss/enroll:** establish a checklist with points of discussion; make certain latest informed consent version is being used; and enroll subject on study.[1]

• **Document/report:** use a template for dictation to complete documentation; use a checklist when proofreading consents; report that the subject is accurately enrolled on the study.[1]

Once the informed consent form is approved by the IRB and any other committee that reviews it, then it is activated and available electronically for use in recruiting study participants, Finn says.

"By putting the document on the website, which is a convenient location for research staff and faculty, then we can ensure the informed consent form they pull up is always the most current, IRB-approved version," Finn adds.

This is an important difference over the hard copy IC process in which a study's filing cabinet might contain several different versions of the informed consent form, and researchers could mistakenly grab the wrong version when enrolling a new participant, notes **Maria Mercado-Cooper,** supervisor of research regulatory systems at UTMD.

"Also, the electronic file contains different language versions of the informed consent form," she says. "If there's a Spanish translation that's been done, then they can grab that one."

"Research subjects who sign informed consent forms hand-sign a paper copy, and we send these to our medical records department, scan the document, store it, and put a barcode on it," she explains.

"It has not only barcoding information, but also the participant's medical information," Finn adds. "And it has the date when the participant signs the consent form, and one more barcode identifies the document as a research document and designates where the document will be stored."

Other information on the IC form is as follows:

— Protocol number

— Date IRB approved the form

— Participant information.

Clinical trial investigators and coordinators can

retrieve the signed informed consent form with electronic access codes, validate their own information and the patient's information, Finn says.

"We make sure the employee's user access ID is current and check the subject's demographic information against the institutional database to make sure we have the right person," says **Matt Lindblom**, MS, manager of research regulatory systems at UTMD.

"We also have a list of eligibility criteria that must be adhered to, and we make available to all research faculty a blank eligibility checklist that they can use as a valuable tool for ensuring the subject is a good candidate for the study," Lindblom adds.

Another helpful compliance tool is a checklist of what to discuss with participants during the informed consent process.

"We give different departments guidance for talking with participants," Mercado-Cooper says.

These points of discussion include the following:

— purpose of the study

— treatment and schedule of the study

— voluntary choices

— risks and benefits and alternative treatment options

— privacy or HIPAA regulations

— any financial coverage

— study withdrawal or completion

— who to contact

— language assistance, if applicable

— optional procedures, if applicable.

The checklist should cover everything the participant needs to know about the study, Mercado-Cooper says.

After a participant is enrolled in the study, a progress note is dictated. Researchers can use an electronic voice system.

"Every office and institution is different," Finn says. "We have a voice-activated dictation system, and our records are dictated and automatically filed in the electronic health record."

Documentation includes these details:

— Is the patient eligible for enrollment?

— Was there an opportunity to discuss this with the doctor?

— Did the subject verbalize understanding of the study?

— Is the informed consent form signed and dated appropriately?

Signed copies of informed consent documents are kept in the medical record, study file, and sponsor file.

Other items pertain to the session number, the study accrual and treatment planning, the patient's height, weight, chemotherapy notations, and documentation that the patient participated in the discussion process and that the study chair and research staff also participated, Finn says.

Another useful compliance tool lists the total accrued registrations.

"It's a double-check that comes at the end of the entire process," Lindblom says.

For instance, in 2010, the number of active protocols open for accrual was 3,303, Mercado-Cooper says.

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

■ Survival skills: experts talk about what to do during economic woes

■ Sharpen Medicare reimbursement processes for trials

■ Improve QI review process

■ Operationalize compliance, following these best practices

■ Electronic solutions: handling e-monitoring

"We get about 40 protocol submission requests bimonthly, which is a huge amount of protocols that come through," she adds. "All of these tools are just to ensure that research regulations are in place and being followed in each of the departments."

REFERENCE:

1. Matza MJ, Finn L, Lindblom MZ, et al. Essential regulatory compliance tools and checklist for the documentation of the informed consent process. Poster presented at the 2010 PRIM&R Advancing Ethical Research Conference, held Dec. 6-8, 2010, in San Diego, CA. ■

CNE/CME QUESTIONS

25. Which of the following is a good strategy for improving financial management of a clinical research site?
    A. Negotiate with sponsors for a 25 to 30-day payment cycle
    B. As subcontractors for Medicare allowance rate prices
    C. Cross-train staff and shift CR coordinators into recruitment work when there are fewer studies
    D. All of the above

26. Which of the following you not want to include in a checklist for the informed consent process?
    A. All of the inclusion criteria have been met (Yes or No)
    B. The informed consent process was performed in a comfortable, quite, and private location
    C. The subject agreed to sign the informed consent form after the investigator agreed to increase compensation for visit time
    D. The subject was given ample time to read the consent form

27. True/False: One of the changes proposed in federal rules about conflicts of interest and research is that research institutions would need to disclose any compensation from outside interests in excess of $15,000.
    A. True
    B. False

28. A three-pronged strategy for improving informed consent process compliance could be labeled as which of the following?
    A. Assess, correct, document
    B. Validate, discuss, document
    C. Validate, confirm, enroll
    D. None of the above