CLINICAL TRIALS ADMINISTRATOR

An essential resource for managers of clinical trials

October 2011: Vol. 9, No. 10
Pages 109-120

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Financial Disclosure: Editor **Melinda Young**, Executive Editor **Michael Harris**, and Nurse Planner **Elizabeth Hill**, DNSc, report no consultant, stockholder, speaker's bureaus, research or other financial relationships with companies having ties to this field of study. Physician Reviewer **Raymond Plodkowski**, MD, has a research affiliation with Orexigen Therapeutics, Abbott Pharmaceuticals, Lilly Pharmaceuticals and GlaxoSmithKline Pharmaceuticals. He is on the speakers bureau of Lilly, GlaxoSmithKline and Novartis.

Data security is costly, complicated & Common Rule changes may not help

HIPAA would be model for all studies

The proposed changes to the Common Rule address an issue that clinical trial organizations have raised since HIPAA's privacy provisions went into effect, but it appears to make the situation even more difficult, some experts say in comments to the U.S. Department of Health and Human Services (HHS).

These proposed changes were published in the Federal Register, on July 25, 2011, as part of an Advanced Notice of Proposed Rulemaking (ANPRM). The Office for Human Research Protections (OHRP) published public comments to the ANPRM online at www.regulations.gov.

HHS proposes these three specific requirements to strengthen protections against informational risks:

1. Data security standards in the HIPAA Security Rule would be the model for research involving identifiable data and data in limited data set form. This means that research with individually identifiable information, including all biospecimens and limited data sets, would need to follow data security standards in using encryption processes and provide safeguards for paper data, as well. When investigators used limited data sets or de-identified information, they would be strictly prohibited from attempting to re-identify the subjects.

2. If investigators see the identifiers but do not record them in the permanent research file, they are considered de-identified or in limited data set form. Using a trusted third party to remove identifiers prior to passing on information to an investigator adds additional complexity and trust issues. "If investigators adhere to the standards for data security and information protection there may be less need for these complex third party relationships," the proposed changes state.

3. HHS would strengthen the enforcement mechanisms under the Common Rule by providing for periodic random retrospective audits and other enforcement tools.

HIPAA's rules for de-identified datasets are too restrictive and hinder the ability to share data for research purposes, writes **Roy Beck**, MD, PhD, executive director of the Jaeb Center for Health Research in Tampa, FL.

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"The biggest aspect of the de-identified dataset we have difficulty with is dates," Beck says. "The de-identified dataset could not have a date of a lab test or visit unless one went through a statistical exercise that showed that within your dataset the probability of someone using that date to track it back to someone is infinitesimally small."

The problem is that it's unclear how to do that.

"So you have to pull the dates out and put in some code to get them in order, but there are certain circumstances where you need to know how one date relates to another date," Beck says. "For example, you need to know the date the person took a medicine and the date of the adverse event."

It's challenging to come up with a scheme where an investigator could replace the dates with some type of number and keep these in sequence with other events, he adds.

"That's what I was responding in terms of it being restrictive," Beck says. "The rest we can handle okay in a de-identified dataset, and we don't have too many problems with it."

According to one physician who commented on the proposed Common Rule changes, the HIPAA Security Rule results in major impediments in day-to-day epidemiological research study activities because of excessively stringent security requirements on computers.

"For this reason, the Department of Epidemiology and Public Health (EPH) at Yale was reviewed and deemed not to be part of the clinical function of the medical school or Yale-New Haven Hospital and its HIPAA coverage severed, so it is no longer considered a HIPAA covered entity," writes **Harvey A. Risch**, MD, PhD, professor of epidemiology at Yale School of Public Health in New Haven, CT.

"This allows EPH-based studies to use standard, good-practices confidentiality and related measures in large-scale epidemiologic studies," Risch continues in his comment. "If HIPAA-standard full computer encryption is required for computers either (a) storing any study data, or (b) even working on data stored elsewhere (e.g., university secure servers), those computers become severely limited in the applications that they can run."

This change would strongly interfere with the ability to conduct high-quality research, Risch concludes.

Another person commenting on the proposed changes notes that it has become very costly to do research precisely because of data protection and analysis.

"How can new investigators afford to do any research if they need to hire a third party to de-identify their data and analyze it?" writes **Marcelle Baaklini**, MA, CCRP, research educator and quality manager at the Cleveland Clinic in Cleveland, OH.

Investigators often need input from information technology experts in order to meet the data security rules, or they need to purchase very costly data security software and services.

"I understand that we need to protect the subject and their public health information, but we need to find ways to help our researchers do this in a less

Clinical Trials Administrator (ISSN# 1544-8460) is published monthly by AHC Media, a division of Thompson Media Group LLC, 3525 Piedmont Road, NE, Building Six, Suite 400, Atlanta, GA 30305. Telephone: (404) 262-7436. Periodicals Postage Paid at Atlanta, GA 30304 and at additional mailing offices.

POSTMASTER: Send address changes to Clinical Trials Administrator, P.O. Box 105109, Atlanta, GA 30348.

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Subscription rates: U.S.A., one year (12 issues), $299. Add $17.95 for shipping & handling. Outside U.S., add $30 per year, total prepaid in U.S. funds. Discounts are available for group subscriptions, multiple copies, site-licenses or electronic distribution. For pricing information, call Tria Kreutzer at 404-262-5482. Back issues, when available, are $50 each. (GST registration number R128870672.)

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expensive manner so they are able to continue their research," Baaklini adds in her comments to HHS.

Investigators who have done research for decades recall a time when the regulatory process was simpler, Baaklini says.

"They still took care to make sure subjects were protected," she adds.

"Now it's so advanced," she says. "I see where it's headed, and it's very costly."

One issue is that principal investigator (PI)-initiated studies are the wave of the future, and, yet, the stringent de-identification and data security requirements create high hurdles for researchers, she notes.

"We desperately need more of those investigator-initiated studies," she says. "We need to find ways to keep research going and make it simpler."

ANPRM suggests the research community comment on specific questions throughout the proposed changes. One question involving informational risks asks if study subjects would be sufficiently protected if investigators are required to adhere to a strict set of data security and information protection standards modeled on the HIPAA rules. The question asks if such standards are appropriate for all types of studies, including social and behavioral research, or whether a better system might employ different standards.

Beck responded with a comment about how the rules for a limited dataset are more reasonable and should be considered instead of the strict set of data security standards modeled on HIPAA's de-identified data set.

HIPAA's definition of what is called a limited data set is not as restrictive as its definition of a de-identified data set, Beck notes.

"It shares a lot of the same aspects of what you cannot include," he adds. "But there are a few you can include: in a limited data set, you can include date of birth or event and their zip code."

Overall, the proposed changes to the Common Rule will be helpful to research organizations, but the changes regarding data security need to be reconsidered, Beck says. ■

Creative IC tool is a user-friendly newsletter

Add color, bullet points, boxes, pictures

In **Caroline Knight's** 20 years of experience, working as a research coordinator, the size of informed consent forms has grown from an average of four pages to about 18 pages. In her estimation, the additional pages have not made it easier to fully inform potential research participants of what to expect in a clinical trial.

"It's ridiculous," says Knight, who is a clinical research specialist for Pen Bay Medical Center in Rockport, ME.

"These are not written for the patients; they're written by attorneys for attorneys," she says. "I'm embarrassed every time I have to hand one to a patient."

Everyone agrees informed consent forms are too long, have too many legal words, and are not readable for most potential research participants. Yet the problem continues, Knight notes.

So Knight decided to create an informed consent tool that would give subjects the necessary information, including required elements of consent, in a reader-friendly format. It would not replace the standard form used by sponsors, investigators, and research institutions, but it would supplement that information and improve the informed consent process.

She has a generic informed consent newsletter that can be adapted to each new study in about two hours, Knight says.

"It helps with patient education," Knight adds. "And the act of creating helps me learn the study better and think it through from a patient's perspective."

Study participants and the IRB have embraced the informed consent tool and sponsors have approved it, as well.

Knight goes over the informed consent newsletter with subjects, reading the headlines, and summarizing what it says.

"Then I leave study participants alone with the newsletter and the full informed consent document," Knight says. "I say, 'Because the informed consent form is difficult to read, this is a supplement to help you. But you should still read the big form; this is a take-away message.'"

Here's how Knight created the informed consent tool:

• **Select a reader-friendly format:** After some research online, she found that a newsletter format was flexible and reader friendly and provided an opportunity for inserting graphics and photos.

"I got access to Microsoft Publisher and used one of their templates for the newsletter, which I created for one of my studies," Knight says.

A newsletter can have color, varying font sizes, boxes, shading, indexes, and other textual and

graphical features that make it appealing to the eye and easier to read and understand.

"I made a generic template of the newsletter and can plug in the information from a new study," Knight says.

• **Include most important elements first:** The newsletter's table of contents shares the front page with a brief discussion of the study and its risks. Also, the bottom part of the page has in a bold, large font the words, "Who to Call?

The numbers listed include "911" for emergencies, plus the study doctor's number at both the research and regular clinic; the research clinic's seven-day-a-week phone number, and the IRB's number in case the subject has any questions about his or her rights.

There also are contact phone numbers on every page, Knight says.

All subject headers are in boldface, larger print and are stated as a question. For instance, the generic form lists this information about risks at the top of the first page of the newsletter:

• "Are there any Risks? All medications have the possibility of complications and side effects. For a detailed list of these, please see page 9 of the informed consent form you will receive. Other risks:

— You might get a bruise where your blood is taken;

— The MRI machine uses a powerful magnet. If you have any metal in your body, this could be a big problem. This will be discussed with you before each MRI is done;

— During the X-ray you will be exposed to some radiation;

— The risks to unborn babies is very big. Therefore, you may not participate in this study if there is any chance of you getting pregnant."

The brief and simplified list of risks is not designed to take the place of informed consent, Knight notes.

"It's a sort of Cliff Notes to the informed consent document," she adds.

• **Give subjects answers to anticipated questions:** The generic newsletter includes a page that talks about what is expected of study participants, using bullet points to cover such items as "Take your study medication exactly as directed" and "Tell the study coordinator about all illnesses and changes in your health."

This section also explains what it means to say study participation is voluntary, saying, "Just because you consent to a research study, doesn't mean you have to finish it. You may discontinue study drug if you don't like the way it makes you feel, if the schedule is not working for you or for no reason at all. You don't even have to give us a reason. However, we do ask that you come in for one last visit. We need to make sure you discontinue the medication in the safest way. We also need for you to return any unused study medication."

Knight also included information in the newsletter about other reasons a study participant might not finish a study, such as if the study doctor decides the study is not in the person's best interest or if there is a problem that crops up in a lab report.

And there even are small sections addressing alternatives to the study, what will happen if new information is learned about the drug, and how subject privacy and confidentiality are handled.

"I put a section in there called, 'Are you just a number?'" Knight says. "It says, 'Well, in a research study, yes, you are just a number! We never submit any documentation about you to the sponsor that has any personal identifiers.'"

Knight said this to study participants for years and thought it would be helpful to include it in the informed consent newsletter.

• **Summarize study events:** The informed consent newsletter has a page that details the visit schedule and procedures performed. It also features an x-ray picture, but could include any photo or drawing pertaining to study procedures.

The schedule might read:

— Screening – up to 21 days before start of study medication

— Day 1 – start of study medication

— Day 14 – this visit can be done any day between 14 and 19 days after day 1.

The key to answering the section header of "What procedures will be done?" is to keep the list simple with single words or short phrases. In Knight's generic newsletter, there is plenty of white space between the bullet point descriptions of procedures.

One example of the list is called "During the screening period," and it includes these items:

— Learn about the study and ask questions
— Medical history
— Physical exam
— Blood draw
— ECG
— MRI and x-ray.

• **Address other issues participants often ask about:** The fourth and last page of the newsletter addresses the study's costs and whether — or

how much — participants are paid.

For instance, under the header, 'How much will this study cost you?' the answer given in the generic newsletter is "Nothing. Any medication or procedure required for the study will be provided by the sponsor to you for no charge. Your insurance will not be billed. For any other medical conditions you might have or any other problems that come up during the study, you will be responsible for those costs the same as before the study."

And Knight includes at the very end of the newsletter a boxed section, titled, "You are contributing to the advancement of medical science."

This part lists a brief reason why research is important: "Research has led to important discoveries that make our lives better." And it has a few bullet-point examples, including new drugs to treat cancer, diabetes, and other diseases, and vaccines.

"We end it by telling them how important they are and the contributions they are making to medical science, and we thank them," Knight says. ■

Avoid common mistakes in the CR contract process

Intellectual property can be tricky

The first step to improving a clinical research site's contracting process is for the clinical research director or coordinator to communicate with the institution's legal professionals about the contract, an expert notes.

"If the person reviewing the contract is a lawyer or paralegal or someone else who is not involved in the day-to-day with clinical trial operations then it's very important for there to be communication between meeting those two people or those two groups," says **Lucy Robins**, JD, attorney at law and legal consultant to the University of Maryland Medical System in Baltimore, MD.

Robins offers this example of why this collaboration is important: "The other day we were meeting with the folks who run the part of our hospital pharmacy that handles the investigational drugs," Robins explains.

"One of the things typically in a contract for the sponsor of a drug study is wording that says, 'If there is any leftover drug at the end of the study, it will be either returned to the sponsor or destroyed by the site, whichever the sponsor says to do,'" she says. "It's almost a reflex to add that the return will be at the sponsor's expense."

But Robins learned at this meeting with pharmacy staff that the destruction or disposition of study drugs can be time-consuming and costly."

There are multiple regulatory requirements for environmental reasons.

"You can't just pour them down the sink," Robins says.

The contract should make clear who is going to pay for the drug disposal, she adds.

"If you spoke to the pharmacy at the site, they might not even want to get involved in doing that disposal of drugs," Robins says. "In this case, it would be very important for the contract to say that we're not obligating them to do so."

If the pharmacy or CR staff are willing to dispose of study drugs in exchange for compensation, then it should be put clearly in the contract that the sponsor will pay for the drugs' disposal, including the costs of extra staff hours and out-of-pocket expenses, she adds.

Robins outlines two other issues that should be addressed in contracts:

* **Intellectual property:** "Particularly if you are an academic medical center, agreements regarding intellectual property are important," Robins says.

"It's important your principal investigators have the ability to publish the study at a time and in a manner they feel is appropriate," she adds. "It's important that the sponsor cannot hold up their right to publication indefinitely."

Sponsors may understand this, but they often will want to delay publication until all sites have closed out.

"This is reasonable, but you have to make sure the clock starts running and doesn't run too long," Robins says.

Also, contracts should address who owns any intellectual property developed at the site. There might be patentable discoveries about the drug or about the disease. Or there might even be something discovered about another condition during the course of the research.

"Research organizations should have a policy about what they're willing to let sponsors have and what they're not willing to let them have," Robins says. "The way this is written in the contract should be consistent with that policy."

When the person handling research contracts is not an attorney and an inconsistency is found in

the intellectual property policy and the contract's wording, then the clinical research staff should ask for assistance from the organization's legal office or from a technology transfer/information technology specialist, she suggests.

"Sponsors are very aggressive in terms of what they want to own, and they'll typically say any invention made in connection with the trial or drug is theirs."

This type of contract language may not have limitations by time or how closely related the invention is to the study, and most organizations would find this to be unacceptably broad language, Robins says.

"The way some of these clauses read, the study drug could be on the market when a doctor who was an investigator in the study comes up with an idea that turns into an invention, and the sponsor's contract wording would have the sponsor owning that invention," she explains. "This is even if the investigator came up with the idea well after the study is over."

• **Budget and payment terms:** Collaboration between lawyers and study teams again is important when a contract is reviewed for budget and payment terms.

"You have to know what the study team's concerns are," Robins says. "I see a lot of contracts where the payment terms say there will be 10% held back until we've resolved all issues."

Sometimes clinical trial teams will ask attorneys to tighten up this language because a particular sponsor is very picky and will waste hours of the study team's time while going over insignificant details, she says.

"You may want to put language in the contract that says the sponsor has to be reasonable or get specific about what the sponsor can hold up payments for," Robins says. "If your site has done its work then you should be paid, and there shouldn't be an issue."

These kinds of contract changes often are more fact-specific than time specific, she notes.

"Sometimes sponsors will say they'll pay at the end of the quarter, and sometimes that's okay and sometimes that's not," Robins says. "Why should you have to wait until 60 days after the end of the quarter to be paid — that's five months after the study subject's visit to get paid."

Robins leaves it up to the study team to review payment terms. If there is a problem, it might be time to suggest a change.

"If they say they have a good relationship with the sponsor then maybe for a study where they only see two patients a year, the payment terms are not a big deal," she says. "I push for what's important to the study and organization."

Clinical research sites also could address concerns about the holdback terms during meeting with sponsors during contract negotiations. It helps if they have something specific to report.

"They could say, 'This is what happened last time: we didn't get our holdback for two years; your people came in six times and kept going over new issues,'" Robins suggests. "You would have more ammunition to negotiate something more specific, but without that you're stuck with the wording of 'reasonableness,' and you won't get the sponsor to agree generally to time limits."

In general, research sites should negotiate for the points that are important to them and their institution and hire attorneys to review the contracts, Robins says.

"The overall idea is that sponsors generally write the contract to represent their best interest on everything in there," she adds. "I tell people they put everything in the contract for a reason, and you need to read it and understand it so you will know what you're getting into." ■

Small sites can thrive with CR; here's how

Financial management system helps

These are trying times for the clinical research industry, but as one small research site has shown, even a small organization can succeed at clinical trials.

"Research directors at a small site have to be able to do everything — from regulatory to finance to patient visits — because there isn't anybody else to delegate to," says **Elise Hartranft**, MSN, CRNP, research director at Heart Specialists of Lancaster in Lancaster, PA.

"With smaller sites you can have personnel issues," she says.

Small sites have to be careful not to understaff or overstaff, and it's difficult to know when it's time to make a personnel change, she adds.

"I have one trial with 30 patients, and this keeps a coordinator busy three-fourths of the time because there are frequent visits," Hartranft says. "People say a study coordinator should handle X number of trials, but it depends on the

number of visits."

Heart Specialists runs six to eight trials at a time, and the research staff typically includes Hartranft and a part-time study coordinator.

"There is a local college where we find undergraduate students who can do six-month co-ops," she adds. "They do the faxing, filing, paperwork, getting charts ready for us for a site visit and that kind of thing."

When the site is between part-time study coordinators, the entire study protocol workload becomes Hartranft's job.

"One of the core pieces for a smaller site would be that your primary research person basically has to be a jack of all trades," she says. "There have been occasions when I've looked at study protocols and had to turn them down because we don't have enough staffing or it's too time-consuming."

Although it seems counterintuitive, one key to succeeding as a small site is learning how to say "no" to studies. Research sites can harm their financial bottom line by taking on studies that drive them into red ink on the accounting balance sheet.

For instance, the research site turned down one study where it would have required five-hour blocks of time for the study coordinator, she says.

"The question was 'Do we hire someone for this study, or do we decline the study?'" Hartranft says. "We decided we would rather decline, but we did talk about taking one of the office nurses and training them on the protocol."

For small sites, it's important to have some staffing flexibility. For instance, Heart Specialists has two nurses who can work on research projects on an as-needed basis.

"They work infrequently, and we can train them on a protocol, paying them a per-patient rate," Hartranft says. "That is our fallback."

Small sites also might decline studies based on equipment needs that are not reimbursed by sponsors.

"We had a protocol where we would need to have certain pieces of lab equipment, and we said, 'We can't do this,'" Hartranft says.

Time frames also can prove problematic to small sites.

"We'd have to think hard about a study where there's a short time window or where we'd have to enroll subjects in the middle of the night or on the weekend, like inpatient or myocardial infarction studies," Hartranft says. "A study that results in doing informed consent in a short period of time requires additional staffing, and the budget would have to be lucrative enough to cover those kinds of costs."

Finding and hiring staff can be challenging for small sites, particularly if they're located in areas where there are a limited number of research sites and research staff.

"There is not a big academic research center in our area," Hartranft notes. "In our county there might be no more than 10-15 people tops that have research experience."

This means new staff likely will need to be trained in clinical research. Since this is the case, Hartranft looks more for a set of characteristics in potential employees than for specific research experience.

For instance, Hartranft will look for employees who are detail-oriented, but also flexible.

An employee who attends to details without flexibility could turn a 30-minute study visit into a two-hour visit, which negatively impacts a study budget, she explains.

"Research coordinators have to be flexible because they could have their day planned out and then something happens," Hartranft says. "A patient ends up in the hospital, and you have to be able to adapt to that."

Small research sites also might invest in clinical trial management systems to help them keep on top of their research finances.

"Our clinical trial management system handles the financial side," Hartranft says. "It tracks patient visits, protocol deviations, and similar things."

It isn't a patient records database, she notes.

"It's financial in nature," she adds. "The system can do analysis."

For instance, as the site's studies increase, the system can analyze workloads and estimate the need and financial ability to add staff. The management system also handles stipends to subjects and can handle budget negotiation data, accounts receivable, general protocol budgets, and research staffing hours, Hartranft says.

The budgeting capability is particularly useful, she notes.

"I can look at a protocol, the procedures for each visit, and put that information in the system," she explains. "It takes information on what a person will perform and how long it will take and then adds in overhead dollars."

From a financial management perspective, it's very useful, she says.

"It's also set up where you can do projec-

tions," Hartranft says. "You can determine how much you will make in the next year based on the studies you have and how many people you think you'll enroll over time."

These projects can better inform staffing decisions.

"If it looks like we're bringing in X work, but the study coordinator an only handle this amount of volume, then that's a way to make your arguments for additional staffing," Hartranft says. "It shows that I can pay this person's salary if I enroll X amount of patients."

Another staffing and efficiency strategy for small research sites involves using inexpensive resources whenever possible. Besides having coop students assist with some of the day-to-day tasks in running a clinical trial office, Hartranft plans to teach them how to use the financial management system.

"The financial management system can do more things, but we haven't had time to put in the data," she explains. "I'm going to see what the students can do to help me enter data in the system so we can utilize it to its full extent." ■

BEST PRACTICES SPOTLIGHT

Make study start-up a smooth-sailing process

Keep documents up-to-date

Everyone in the clinical research industry has heard the dismal statistic of how one out of five clinical trial sites never enroll a single patient. Many physicians have been drawn to doing a study in addition to their fulltime clinical practice, and they often decide to give this up after one or two trials.

So what makes a small physician's practice successful in the research business?

"In order to be successful, the most important thing is to be well organized and have a very efficient site start-up process," says **Arthur Waldbaum**, MD, clinical investigator at Downtown Women's Health Care in Denver, CO.

Waldbaum has a one-doctor private ob-gyn practice. He's been in private clinical practice since 1978 and has done research since 1988. The majority of his more than 120 studies have been in the top 50% and often the top 10% to 20% in enrollment, he says.

"I gradually started doing more research, and over the last 15 years, I primarily do clinical research with less general ob-gyn," he says.

There have been many challenges with his research business, and Waldbaum has been a hands-on manager who likes to do the work efficiently and on time.

"There are advantages to having a smaller practice, as well as to being more efficient in doing it," he says.

When Waldbaum began running clinical trials, there was an occasional study, but it's different now, he adds.

"It's much different when you are doing 10 to 20 studies at a time, which is what we're doing now," Waldbaum says. "You have to be a lot more organized and efficient in doing the study start-up process."

Waldbaum has developed best practices over the years, including these tips:

• **Put documents in place:** "The first element is to make sure all documents are in place, all regulatory documents, so you get IRB approval in a timely fashion," he says. "And make sure you complete all the documents and have CVs and medical licenses up-to-date."

Each study has its own regulatory documents, and each IRB has its own specific forms to be completed. Waldbaum typically uses a central IRB.

Investigators and clinical research staff should prepare well for creating advertisements and using telephone screening questionnaires before they obtain IRB approval.

• **Meticulously prepare budget and contract items:** "There's nothing worse than being ready to start the study and going to the investigator meeting and not having your contract set or budget set, so you're starting to work on those then," Waldbaum says.

"You need to make sure you have developed a budget in advance and have all the line items there, so you know it will be profitable to do the study," he adds.

Waldbaum has a list of items he needs to negotiate for the budget, and he knows from experience what to look for in contracts. Examples of items to include in a budget are these:

— payments for line items

— ancillary services
— start-up fee
— initiation payment
— amount withheld
— frequency of payments
— advertising budget
— how screen failures are paid.

"I use a checklist because I don't want to lose any of those items," he says. "If you have those budgetary items outlined in advance and you make sure you have the required insurance requirements, then you're comfortable," Waldbaum says.

This is a necessary, if time consuming process. Waldbaum typically spends several days going over this list with the study template and budget.

"Before I go back to the company, I need to know what to ask for," he says. "Then it's a process of time and how much negotiation is needed between the sponsor and site."

Investigators should remember that whatever budget is presented by the sponsor has room for negotiation, he adds.

• **Prepare office and staff for the study:** "Hopefully, even before the investigator meeting, you should make sure everything in the office is prepared for the study," Waldbaum says. "We need to know which laboratory will be used, what type of equipment they need to make sure all equipment has been recently calibrated, and they need to make sure couriers — whether its UPS or FedEx — are in place."

The research site should have a primary coordinator and a back-up coordinator for the study. And their documents should be in order, showing the proper training for hazardous waste and human subjects protection, he adds.

"Make sure your site has the proper storage space and freezers, refrigerators, so forth," Waldbaum says. "This is so we don't find out later on that we don't have space for the drug or encounter anything that might delay the process once we're ready to start."

• **Begin recruitment as soon as the IRB issues its approval:** "If we have the IRB approval, I like to start looking at subject recruitment before the meeting starts," Waldbaum says. "We look into our database of patients and previous study participants to see of any would qualify for this type of study, and we'll even start calling and sending out letters to patients in our database so we'll have subjects lined up in advance."

Waldbaum also will begin creating an advertising plan, making decisions about whether to run ads on local media and which venues to use.

"We'll start preparation on which types of venues we think would be more beneficial for this type of study, and all of those can be done in advance, as well," he says.

"Once we know how much is in the advertising budget, some of the decisions we'll make are based on the budget, and some are based on the age of the study's subjects," he adds. "For younger subjects, we might do more Internet advertising, and for older subjects, we'll run ads in newspapers and on TV."

• **Attend the investigator meeting:** "Be sure you and your coordinator attend the investigator meeting," Waldbaum advises. "In some cases the investigator doesn't go to the meeting, or the coordinator doesn't go, and that delays the process because the sponsor will have a separate site visit scheduled before starting the trial."

"You will want all of your questions answered, including what the study timelines are and what you need clarified about the inclusion/exclusion criteria."

The investigator meeting is a good opportunity for learning more about the study's nuances, such as the enrollment criteria.

"There's nothing worse than screening patients and bringing them into the office and then finding out they don't qualify based on something in their history," Waldbaum says.

So the key is to write a precise screening script that includes any inclusion/exclusion details explained at the investigator meeting.

• **Follow-up on loose ends:** Although Waldbaum's research site is small, he makes certain he has fulltime research coordinators who are well-trained and can handle the new study.

"I don't do PRN staff; I have not found that to be very successful," he says. "Research coordinators are very important for each study, and they do a lot of work."

Waldbaum will not start a study unless he has the proper staffing to deal with it.

There might be a few additional documents to complete, and the site might have to create a source document, although sponsors typically provide this, he adds.

"The coordinator and principal investigator may have to do online training to make sure we know how to use the electronic CRF," Waldbaum says. "But other than familiarizing ourselves with all the documents and being more active in getting ads in place, we can begin more actively screening patients and should be ready to start enrolling at that point." ■

BEST PRACTICES SPOTLIGHT

Create a more efficient source document form

Start with creating templates

'Be prepared' is a clinical trial coordinator's best practice motto. This means finding or creating templates that will facilitate faster, more efficient, and better quality data collection.

"Generally, the best thing to do is to try to get a copy of the electronic data capture (EDC) forms and whatever kind of template the sponsor can provide for you, and, of course, the protocol," says **Deanna M. Hill**, NCMA, CCRC, clinical research coordinator-2, at Emory University in Atlanta, GA.

"I like to read the protocol first because it has the extra details the EDC is not going to tell you," Hill says. This information might include the order of procedures, she adds.

From the EDC, research coordinators will find demographics and disease information.

"It's essential you get all of this information and sit down to pull it all together," Hill advises.

For this process, Hill refers to master templates, which can be tweaked for each study.

Hill describes the steps she follows in creating and revising templates:

1. Tailor existing and create new templates.

"There are all kinds of templates for medications, adverse events, and even product performance," Hill says. "You can see other templates, but you need to tailor them to your liking and your needs."

When creating new templates, research coordinators should think about which tasks they do most often in their practice, focusing on those that do not change much, she suggests.

"If you're doing different studies and keep seeing the same procedure over and over again, then you know that's something you have to recreate each time," Hill says. "So instead, hold onto the template and make sure it's the same as what the sponsor wants you to capture."

Use a coordinator checklist to see which procedures have to be done throughout the study process, including items like a physical exam. Then tailor templates to what will work best for your site and study, she adds.

"The best templates hardly ever change, needing maybe one or two adjustments," Hill says. "But they're standard."

It's also important to have the study team using the same templates, avoiding confusion.

"Whenever I make templates or put together source documents for another study or another coordinator, we all use the same template," Hill says. "So we all know independently what has to be filled out."

This is useful in the event that one study coordinator is covering for another one who is out sick or on vacation, she adds.

For each new study, research staff should review the template and make themselves familiar with the data being collected.

2. Review worksheets online.

"Look at other people's worksheets, and see how they were put together," Hill says. "Look at what looks nice on the page, what flows well, and tailor it that way."

The order and style of these worksheets are subjective. What looks nice and seems to flow in one person's opinion might need to be moved and revised according to another person, she notes.

"I put the title and sponsor and patient's name on top, and the other information is below it," Hill says. "I use boldfaced information, and any special instructions are put in parentheses next to it."

For example, Hill uses a brief enrollment visit template that is tailored to each study and visit. A sample template has these boldfaced checkbox items:

- Verify inclusion exclusion criteria
- Call [investigator] to inform [that] possible patient being pre-screened (telephone number)
- Sign consent and process form

— Make 2 copies (One for subject and one for chart)

- EKG 3 Lead

— 2 EKGs are to be obtained and measured with screening tool

- Medical history

— Complete enrollment source packet (7 pages)

- Medications

— Current medications to be completed on conmed log

- Fill out clinical trial participation form fax with consent to OCR (8-4989)
- Surface EKG recorded with each VF induction/conversion during implant
- Remind physician to order Standing P/A and Lateral Chest X-ray after implant
- Medications

— Get copy of current meds from Power chart or subject

— Pre-implantation medications taken must be recorded

— Medications given during implant must be recorded

— Medications given post implant must be recorded.

3. Put template through a trial run.

Through trial and error, research coordinators can improve their templates, Hill says.

The first patient is the next test of the study-specific template.

"The first patient is the hardest one; there's always something missing or something in it you don't need," Hill says.

These findings are lessons in editing and checks and balances.

"Look at the EDC and look at what the sponsor has given you," Hill suggests. "You think it's perfect, so you should work with it and see if it works."

Research coordinators always can make adjustments after the first couple of patients, she adds.

"Maybe there is a question that needs to be asked of the patient, and you didn't pick up on it until it's too late," Hill says. "So you can scribble that information in it."

Another good checks and balance is to ask other staff for feedback.

"They're good at giving feedback because everyone wants something they can work with," Hill says.

4. Keep template for future use.

Once a study ends, research coordinators can file and save the template they've modified for that study.

"I keep an electronic copy on my Desktop, and I make a paper copy that I keep in a binder," Hill says. "Whenever an assistant or student needs to fill a binder they can make copies and give it to everyone using the study."

Also, the completed templates are kept in patient binders and are used as original source documentation, she adds.

They can provide a ready-made template for the next study in that disease area or which uses the same patient population.

For instance, a template on demographics and medical history might be revised to reflect a study's cardiovascular focus. Hill uses a master demographics template that includes these main sections:

- Demographics, including gender, height, age, birthdate, and race
- Cardiovascular history, including etiology and atrial fibrillation use
- Coronary heart disease, listing the most recent myocardial infarction
- Prior cardiac intervention, listing dates of recent CABG or PTCA procedures
- Ventricular arrhythmia history
- Other underlying disease, including diabetes, chronic lung disease, hypertension, peripheral vascular disease, and others
- ECG diagnosis with date and measurements
- Optimization of heart failure medication, asking about Ace inhibitors and beta blockers
- Visit comments.

Hill has received positive feedback about the templates.

"Monitors seem really pleased with them," she says. "I color code the pages, and they like that." ■

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

- ■ Researchers argue against biospecimen IC changes
- ■ Common Rule proposal elicits controversy
- ■ QI project focuses on documentation
- ■ Site's recruitment practices create winning strategy
- ■ Coordinator training tips change with the times

CNE/CME QUESTIONS

1. The proposed changes to the Common Rule address data security. Which of the following is included in these proposed changes?
   A. Data security standards in the HIPAA Security Rule would be the model for research involving identifiable data and data in limited data set form
   B. Research with individually identifiable information, including all biospecimens and limited data sets, would need to follow data security standards in using encryption processes and provide safeguards for paper data, as well
   C. When investigators use limited data sets or de-identified information, they would be strictly prohibited from attempting to re-identify the subjects
   D. All of the above

2. Clinical trial contract negotiation can identify important areas of disagreement. According to a lawyer expert, which of the following is a good example of why contracts should be carefully screened?
   A. A contract might have the site pay partly for the cost of the monitoring visits
   B. A contract might require a study site to return or destroy all unused study medication, but fail to state that the sponsor would pay for this disposal, leaving the site stuck with the expense
   C. A contract might give investigators a deadline for when to publish a first article for a study
   D. None of the above

3. Which of the following are good examples of items to include in a study budget?
   A. Payments for line items and ancillary services
   B. Start-up fee and initiation payment
   C. Frequency of payments and advertising budget
   D. All of the above

4. True or False: According to a research director at a small medical research site, a key to success as a small study site is staffing flexibility.
   A. True
   B. False