CLINICAL TRIALS
ADMINISTRATOR
An essential resource for managers of clinical trials

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IN THIS ISSUE

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The devil is in the details when it comes to research coordinators

Study sponsor outlines a dream coordinator's job description

The audit team from Johnson & Johnson (J&J) Pharmaceutical Research and Development in San Diego has never hired a clinical research coordinator (CRC), but that doesn't mean it doesn't have some very strong opinions about the skills a good one should have.

James J. Rava, the associate director of global quality assurance for the J&J unit, and **Cheryl Zigrand**, a senior associate for global quality assurance, practically in unison state that the No. 1 attribute of a great CRC is being detail-oriented.

"They have to be very organized, almost obsessive-compulsive," Rava says. "A protocol requires a lot of making sure that all goes according to plan. The physicians, who are the principal investigators, won't be making sure of that. The nurse has to."

Why a nurse? Rava says that while others might make good coordinators, most protocols require tasks that need a licensed professional to do — such as blood draws.

"A medical assistant can take vital signs, but a nurse can assess them," he says. "Nurses can do more sophisticated procedures and make a clear initial evaluation based on that patient's history."

Other credentials that work well in the role include physicians' assistants and nurse practitioners.

"If there is a phase one trial with 15 subjects, and every one of them needs a blood draw every half hour, someone has to be there to do it," adds Zigrand. "It's great if the physician has the time to do that, but they are usually busier than that. You have to have someone else who is licensed to perform that task in that state there to do that task."

Make it a team effort

If you don't have a description for the position — or for any position — consider letting the existing employees create it, says **Helen M. Pavilonis**, RN, MSN, OCN, clinical research manager at the Comprehensive Cancer Center at Duke University in Durham, NC.

"Then you can revise and tweak it by adding and deleting," she adds.

Pavilonis also has picked the brains of former clinical trial coordinators, looked at sample job descriptions from the Cancer and Leukemia Group B research cooperative, and checked her descriptions with other groups at Duke.

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Editorial Questions

Questions or comments?
Call **Alison Allen** at (404) 262-5431.

"We are a huge institution, and every disease has its own research going on," she explains. "And for every disease, there are variations in what they do. We have seven teams in oncology alone."

One example of how the job descriptions can differ: for cancer research, the research subjects are always sick patients; while for other diseases, phase one study subjects are likely to be healthy volunteers. That can make a huge difference to how a coordinator will enroll research subjects, she says.

Be specific about job duties

There's probably no one who fits the ideal mold for research coordinators completely. Despite that, it's still important to have a job description that outlines what the ideal person would do, says **Elizabeth E. Hill**, RN, DNSc, director of the clinical research management program and assistant professor at Duke's School of Nursing.

"I have found that if the job description isn't clearly spelled out, the employee can simply refuse to do something that is a critical piece of your overall requirement," she says.

"Or they may not realize it's even something they are supposed to be doing, and no one knows they haven't done it until you need a key piece of information that isn't there," Hill explains.

She draws a parallel between creating a job description and doing research.

"When I'm doing research or helping other people develop a protocol, I always encourage them to do at least a simple pilot. But if they can't do that for some reason, I tell them to really step through — one piece at a time — everything that will go on in the study and document it so they can identify problems up front and won't miss important things that need to be done. I do the same thing, more or less, with a job description," Hill adds.

"First, I need to know clearly what knowledge base and skills I need," she continues. "So I think through that carefully, a piece at a time. As an extreme example, suppose part of the job involves driving blood samples to a distal location. Then I have to make sure they have a valid driver's license and a car."

Pavilonis cites another reason for making sure you have an accurate job description: Evaluations usually are based on them.

"You have to make sure you have it right or

how can you determine how well someone is doing?" she asks.

17 responsibilities for the dream candidate

Zigrand and Rava say they have thought a lot about what every great CRC needs to be able to do and have come up with a list of duties and responsibilities that administrators should think about inserting into their coordinator job descriptions.

1. Coordinates trials in accordance with established protocols, Food and Drug Administration (FDA) regulations, institutional policies, and ethical clinical practice. Of all of those, Zigrand thinks that the FDA piece is the weakest link at the sites she visits. "We often get questions about some of the audit observations we make and have to point out to them the FDA regulations that say they have to do something in a particular way," she says. "They aren't always aware of the regulations under which they should be working."

2. Determines patients' clinical protocol eligibility. The right patients have to be in a study not just to make sure that the study results are accurate, but also because of patient safety issues, says Zigrand. The wrong patient taking an experimental drug can have disastrous, even deadly, consequences.

3. Maintains research supplies inventory. "That could mean the case report forms that they transcribe the source data to, sample kits for the blood draws, and the medication itself," says Zigrand. "The coordinator has to keep very good track of all that comes in and all that goes out. Everything has to be documented."

4. Collects all protocol data.

5. Assists with the necessary staff inservices for protocols.

6. Communicates protocol needs to other departments. Many times, the patients for a study don't come from the practice that is conducting it but are referred by ancillary groups, says Rava. The coordinator has to be a great communicator and be able to communicate to other departments or other offices what the needs are so that the right people are referred.

7. Interacts with patients directly during clinic visits and by phone. "They have to learn the protocol well enough that they can communicate it to patients in terms they can understand," Zigrand says.

It requires a certain flexibility, says Rava, being able to explain the consent form to all test subjects in their native language and in terms they can understand and then turn around and discuss the same subject with a physician on a peer-to-peer level.

8. Analyzes and evaluates clinical data. Having someone who can just tick the appropriate box on a form isn't enough, Rava says. "We don't need them to be biostatisticians, but they have to be alert about what patients experience during the study and determine if there are any events that are occurring across the patient base. They have to be able to trend it both on paper and in their heads."

9. Develops and maintains organized record files. "We have to have great files, not just for the patient's own well being, but because we and the FDA will audit them," he says. "If it wasn't documented, then when we come two years later, as far as we are concerned, it didn't happen."

10. Collects or supervises data collection for study documents. Progress and visit notes and other source documents have to be clearly transcribed, consolidated, and configured for the study forms, Rava says.

11. Demonstrates an ability to set priorities and to achieve maximum productivity and efficiency.

12. Maintains professional licensure and competency.

13. Willingness and ability to travel to the sponsor's investigator meetings prior to the onset of the study.

14. Demonstrates the ability to follow through completely and effectively with a minimum amount of direct supervision. Rava says that for most physicians, conducting a study is a second job. "He or she makes rounds, has clinic patients, and may be doing other studies," he says. "The coordinator won't get to see the physician a lot, so being a self-starter and self-motivator is important."

15. Maintains strict confidentiality in compliance with the Health Insurance Portability and Accountability Act.

16. Have appropriate communication skills that further the goal of sharing information, knowledge, and responsibilities of the study with other research team members. "The CRC runs the study," says Rava. "They have to be able to communicate its strengths and weaknesses to other team members."

17. Be a mentor. "When someone new starts, the coordinator has to be able to get that person up to speed," Rava says. In addition, all team members have to be able to handle other team roles and fill when necessary.

Never assume the job description is static,

though. "For us, our research nursing descriptions have largely stayed the same," Pavilonis notes. "But our coordinator position has had some minor modifications." Review it yearly, she suggests, and whenever you hire someone new, take another look at it. ■

Finders keepers: How to retain good research staff

Small company has learned big lessons

Carolinas Research Associates in Charlotte, NC, is a small company: there is a total of eight staff members, four of whom are research coordinators. Over the seven years the company has been in business, CEO **Yvonne McCracken**, MPH, and co-founder **Sara Brandon** have discovered a few truths about out how to find and keep good employees.

• **Don't limit yourself.** While many people prefer to have RNs run their research, Brandon says an RN doesn't automatically make for a great research coordinator. "It's nice if they have a health care background, but more important is that they have done college work in biology or chemistry," she says. "We even have a coordinator who is a high school graduate, and she's the strongest one we have."

For hospitals, it can be different, McCracken says. In those cases, an RN may be more important. "We do outpatient work, and we don't want them to be nurses. We want them to be study coordinators." What really makes a good coordinator is simply someone with a health care background who is extremely detail-oriented, bright, flexible, and "able to juggle a lot of different tasks," she says.

• **Don't be afraid of first jobbers.** McCracken says they have had successful coordinators come right from college. One of the benefits of hiring someone new to the work force is the ability to train him or her to do a job how you want it done, she adds.

• **Use your universities.** Getting involved in college internship programs is another way to find good employees. "It's great when you can mold someone like that," says McCracken. "Experience can be great for bringing you new ideas, but we like to do things our way." There are certain elements that make for good clinical research practices, Brandon adds, "We like to go beyond that. We do things in a way that is different, but that we think makes us a cut above the rest."

• **Ask the right questions.** Interviews have changed over the years at Carolinas Research. McCracken handles initial interviews. "I tell them who we are, what we do and what the position entails, and give them a job description to review and make notes on," she notes. They meet with both her and Brandon for the second go-around, at which "they do most of the talking," says McCracken.

"We ask them open-ended questions so we can figure out if they are a team player, what their interest level is, and what they understand about the position." **(See list of sample behavioral interview questions, p. 5.)** Answers can be surprising, she adds.

"Sometimes people think research sounds interesting, but they get started and hate it. We want them to understand our expectations," McCracken points out.

• **Consider peer interviews.** If the candidate is still interested and interesting, then the next interview is held with staff members. "Meeting with them is so that they can see the way things work and ask questions they might not feel comfortable asking us," McCracken explains. It also gives the staff a chance to size up the candidate.

While it hasn't happened yet, McCracken says that if the staff didn't like a candidate, she and Brandon would take a very close look at him or her again.

"As long as it wasn't for some reason, like the person used to date someone's sister, it would carry a lot of weight with us," she says.

Don't micromanage your staff

• **Show you respect them.** Staff members, once established, are given a lot of autonomy and responsibility. "We integrate them as much as possible in the running of the business," says McCracken.

Both she and Brandon came from larger organizations before they started their company. One thing they don't miss and make sure they don't perpetrate — micromanagement. Nothing makes for unhappy employees like second-guessing what they do or looking over their shoulders to make sure they do it right, she says.

• **Let staff know they are special.** "We know that without our staff, we wouldn't be here," says

Behavioral Interview Questions

1. Tell me about the hardest day you had on your last job.
2. Tell me about a time when you were able to solve a really big problem.
3. Describe a situation when you had to work with a difficult customer or co-worker.
4. Describe a time when you had to get someone to accept an unpopular idea or decision.
5. Describe a situation where you had to motivate someone.
6. Tell me about a time when you had to juggle multiple tasks or responsibilities.
7. Tell me about the busiest day you had in your current position.
8. Give an example of when you had to think on your feet.
9. Tell me about the day or project you view as your biggest success.
10. Describe a situation where you had to delay action because you didn't have all the information you needed.

Source: Carolinas Research Associates, Charlotte, NC.

Brandon. "We strive to make sure they know that."

The company holds regular retreats, close the office for a staff fun day over the Christmas holiday period, and make sure that bonuses are shared liberally. Indeed, although larger organizations may be able to provide better base salaries, they may not have the flexibility of a small organization in terms of bonuses. One staff member left, but returned after nine months because she didn't do as well financially at the other company.

"They couldn't give her the bonuses we could," recalls McCracken.

• **Provide all the opportunities for job growth you can.** This is probably the only area in which larger organizations have an edge over smaller ones. But still, says McCracken, "we make sure we give them as many growth opportunities as we can. We want them to learn new things, and once they are established here, we're happy to let them do whatever they want."

• **Evaluate problem positions.** While most of the staff have been with the company for a long time, there is one position at Carolinas Research that has had a lot of turnover. "That's very costly to us," Brandon says.

"It was a position where the person rotated through different offices. Now we make sure they are well integrated into this office before they are turned loose to work on their own. We think that will build a team atmosphere even for those who are working off site," she adds.

• **Encourage professional memberships.** Carolinas Research pays for dues in professional organizations, certification tests, and trips to professional and business meetings.

• **Improve benefits as you can.** As a small organization, there are some things that can't be provided for staff — such as on-site child care. But this year, the company is instituting 401(K) programs. They already have profit sharing.

• **Celebrate great work.** At the last retreat, staff mentioned the pride they have in what they do. It helps, too, that their sponsors recognize the quality of their product. Brandon says that one coordinator was asked to come to a major pharmaceutical company to explain how she recruited patients for studies. Such kudos are touted and celebrated by the whole staff.

• **Keep it fun.** If the job isn't fun, who will want to work there? If it is fun, problems are more easily accepted and staff are more willing to participate in finding solutions.

The good news for all research organizations is that it seems to be getting easier to find coordinators and other research staff, says Brandon.

"I've talked to people all across the country, and there is a general sense that recruiting is getting easier," she says. "There are now programs at colleges that teach about research coordinator positions. There is a curriculum at some schools — like Durham Tech — and talk that it might be added to some nursing schools. Now, when you put an ad in the paper for a coordinator, there is more awareness about what it entails. Before, you'd put an ad in the paper and get people without a clue." ■

Spend a dollar on training, save a few more on fines

Train your staff, or risk noncompliance

Do you want a compliant clinical research program? Start with training and education, clinical research administrators advise. Otherwise,

you could end up paying millions if your staff make a critical mistake, such as improper billing.

Training isn't cheap. Some programs spend $20,000 or more on a one-day off-site training event held every few months. Some programs report spending $80,000 and up in a year on direct costs for training, education, and auditing.

"I expect these costs to rise as the requirements for institutional accreditation begin to be implemented," says **Lynette M. Schenkel**, administrative director of research and academic affairs at Beth Israel Deaconess Medical Center in Boston.

You want to spend your dollars wisely, so consider these suggestions from your peers:

• **Assign mentors.** The Jacksonville (FL) Center for Clinical Research pairs new coordinators with an experienced mentor during training, says **Michael Koren**, MD, FACC, chief executive officer.

The mentor determines how the individual obtains training, he says. "It has to do with their previous experience and the type of setting they're involved with," Koren says.

• **Use the web.** At the Jacksonville center, a large portion of the training is a web site where staff, including physicians, can access a series of questions to assess their knowledge of various clinical trial issues, including regulatory issues and clinical issues. Different tracks have been created for different staff members. The web site was developed internally, but other programs can access the site for a $2,500 first-year site license fee and $1,000 annual fee in following years, which includes training of flagship staff.

During employees' orientation, they are introduced to the web site, which can be accessed at computer stations in the facility, Koren says.

The site is self-directed, and the facility's standard operating procedures have been integrated into it, he explains. "If you don't know the answer, the program takes you to where you can find the answers."

• **Consider off-site in-house training.** Koren's facility offers an intense training seminar twice a year at a restaurant, hotel, or staff person's house. A comprehensive list of topics is covered, he says. The costs range from $15,000-$20,000, which covers meals and a night at a hotel for 50-60 staff members, plus speakers' fees.

• **Supplement with independent training providers.** Three advantages of independent training providers are that they can come to you, tailor their program to suit your needs, and offer a fresh voice, Schenkel says.

"Instead of your research community hearing the same people sometimes drone on about the same things, independent training providers have a different way of presenting the same information and can provide recognizable, yet anonymous, case studies from other institutions," she says.

The disadvantages is that no independent provider is ever going to know the nitty-gritty details of your operations, such as your systems support, Schenkel says. "That is why use of independent providers should be an important supplement, but not your sole training imitative," she says.

• **Look at on-line certification programs.** Beth Israel Deaconess requires all of its researchers, clinical research staff, investigational review board (IRB) committee members, and IRB staff to go through an internally developed on-line certification program.

The certification asks a series of questions that the users must answer, Schenkel says. If a user answers incorrectly, the correct information is pulled up on-screen in a dialog box that he or she must read through, she says. Subsequently, the user returns to the certification screens and correctly responds to the question before moving on.

"This assures the institution of a basic level of knowledge on the part of all individuals engaged in or supporting the process of clinical research," Schenkel says.

Beth Israel Deaconess requires recertification on an annual basis.

"The only disadvantage I can perceive in this process is that if you have an individual who is very brand new to clinical research, they may not learn enough from the on-line certification process," Schenkel says.

• **Use national trade associations.** Supplement your training with participation in national trade associations, such as the Public Responsibility in Medicine and Research and the Applied Research Ethics National Association, both based in Boston, Schenkel suggests.

"It provides staff with focused time for education, away from the distractions of their regular day-to-day work," she says. "It allows them to network and understand the importance of good clinical research at a national level, rather than their everyday view of the clinical research world."

In addition, Beth Israel Deaconess regularly sends staff to regional and teleconference meetings, she says. And there is a final step to training

Anchor your training program with Ethics 101

Start with ethics, peers advise

When selecting educational topics for your clinical research staff and investigational review board (IRB) members, where do you start?

Begin with the ethics of clinical research, advises **Lynette M. Schenkel**, administrative director of research and academic affairs at Beth Israel Deaconess Medical Center in Boston. For example, explain "why it is so vital to engage in the sometimes seemingly redundant processes in order to protect human participants," she says.

For the clinical research staff, Beth Israel Deaconess is implementing weekly training, Schenkel reports. The first meeting of the month will be mandatory and will last one hour and 15 minutes. It will provide some food and possibly continuing education credit and risk management credit, Schenkel says.

"Even if they are mandatory, you have to provide incentives," she says.

The meeting will focus on administrative aspects of clinical research, dealing with the IRB, and dealing with the Clinical Research Office in areas such as contracts, budgeting, and case report forms.

"The rest of the weekly meetings will be more informal, brown-bag sessions related to the first-of-the-month topic," Schenkel explains.

The facility already has been offering these types of sessions to administrative staff, she says.

"There's much better discussions and exchange of ideas and questions at the information sessions," Schenkel says. "People aren't afraid to speak up."

For the clinical staff, discuss good clinical practices, including their relationship with the principal investigator, other research staff, the IRB staff, and most importantly, the patient, Schenkel says.

Discuss the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use guidelines for the Standards of Good Clinical Practice, suggests **Selika Gutierrez**, RN, BSN, CNS, ACNPc, program director at Rush-Presbyterian St. Luke's Medical Center in Chicago.

Consider these suggestions for other topics from Gutierrez: explanation of a clinical trial and what it entails, IRB standards for conducting a clinical trial, new Health Insurance Portability and Accountability Act policy and privacy acts, roles of team members such as principal investigator and research coordinators; and for administrators, information on how to conduct interrater reliability training for all staff.

While education of staff is ongoing, Beth Israel Deaconess has designated training for IRB staff at least bimonthly. According to Schenkel, that training covers:

✔ the staff's relationship to the committee, including what a committee does, whom a committee is composed of, and what are the support processes in which they engage to assist the committee;

✔ the IRB office and its staff, including the operations of the day-to-day jobs in which they function;

✔ the staff's relationship to the researchers, including how, when, what, and why to communicate with the researchers; how to represent the committee and the researchers to each other; and how to be an effective conduit for communication between the "sometimes anxious researcher" and the committee.

Although the development of training and education programs can be time- and resource-intensive, they are critical elements of your program, experts advise.

"There is nothing that substitutes for having your own in-house training program," Schenkel emphasizes. ■

and education, Schenkel emphasizes.

Use spot checks to ensure staff are correctly applying institutional and regulatory requirements, she says.

You will realize a payoff when your staff keep your program compliant, Schenkel maintains.

"A good training and education program does not come without institutional commitment and investment, but is worth all the accompanying headaches when the results are realized," she says.

[Editor's note: For information on the license for the web site developed by the Jacksonville Center for Clinical Research, contact Gary Woods at (904) 739-9057.] ■

Do they really understand your authorization form?

Privacy notices don't set the standard

In cities all over the country, Health Insurance Portability and Accountability Act (HIPAA) privacy notices are being shoved into the hands of patients. These notices, presumably explain clearly what HIPAA is and the rights that John and Jane Q. Public now have.

They run the gamut, from eight-page tomes

that detail the law verbatim to two-page summaries that hit the high points and then ask the patient to sign a form acknowledging that these new rights were explained.

Regardless of the length, the forms seem to have one thing in common: They're difficult to understand.

One readability expert found that privacy notices are written at levels most likely to go right over the general public's head. So if your authorization form is modeled after a privacy notice, you may want to think about revising it.

Mark Hochhauser, PhD, an independent readability consultant in Golden Valley, MN, analyzed 31 actual HIPAA privacy notices and discovered that most were written at college levels.

According to recent census data, 85% of adults have only a high school degree. He cites research that asserts that many people read three to five grades lower than their highest degree earned, which would mean high school graduates typically read at a seventh- to ninth-grade level. The notices Hochhauser analyzed were written at a second- to fourth-year college level.

Even those with college degrees may be hard pressed to understand some of the notices floating around. "That HIPAA privacy notices were written at a college reading level means only that they'll be harder for most people to read and understand," he explains.

"It does not mean that anyone with a college degree can understand them and anyone without a college degree cannot. You can major in anything from art to zoology in college, and not everyone with a college degree comes out with the same vocabulary or way of thinking. My PhD in psychology is of little help if I'm trying to understand a document full of legal or medical jargon. I just don't have the vocabulary for those terms. And why should I?"

The biggest problem seemed to be sentence length and word choice. "The sentences are too long and have too many long and uncommon words," Hochhauser asserts.

The average length of sentences for the notices analyzed was 25.2 words per sentence. One example from Hochhauser's research contained 72 words:

> "Your health information may be used for research purposes, but only if (1) the privacy aspects of the research have been reviewed and approved by a special Privacy Board or Institutional Review Board and the Board can legally waive patients' authorization otherwise required by the Privacy Regulations; (2) the research is collecting information for a research proposal; (3) the research occurs after your death; or (4) if you give written authorization for the use or disclosure."

Research suggests that sentences that are easily understood contain 15-20 words per sentence.

In addition to length, the example contained words that are not commonly used (e.g., authorization, disclosure) and the names of two entities with which the public is likely not to be familiar (privacy board and institutional review board). Hochhauser used *The Educator's Word Frequency Guide* to create a list of common and uncommon words.

"Privacy notices are supposed to be written in plain language, but there are no penalties if the notices are written in legal jargon," he says.

"I've seen organizations send out press releases touting that they are 'HIPAA-compliant,' at least with respect to how they handle personal health information, even though their privacy notices are almost incomprehensible. So they claim that they're compliant even when they are noncompliant with a major part of HIPAA. How can they be in compliance if their members can't understand their privacy notices?" Hochhauser asks.

Keep It Simple

Here are a few tips to help you draft a readable and understandable privacy notice or authorization form:

- ☐ **Sentence length:** 15 to 20 words.
- ☐ **Word choice:** Use everyday words.
- ☐ **Sentence complexity:** short with short words, short with a few long words, or medium with a few long words.
- ☐ **Document design:** layered — short, one-page summary accompanied by longer, more detailed notice.

Source: Mark Hochhauser, PhD, Golden Valley, MN.

The rest of the story

Though sentence structure and word choice are important, it may not tell the whole story. How a

(Continued on page 10)

Sample HIPAA Authorization Form

Protocol Title:

Principal Investigator:

AUTHORIZATION TO SHARE PERSONAL HEALTH INFORMATION IN RESEARCH

The word "you" means both the person who takes part in the research, and the person who gives permission to be in the research. This form and the attached research consent form need to be kept together.

We are asking you to take part in the research described in the attached consent form. To do this research, we need to collect health information that identifies you. We may collect the results of tests, questionnaires, and interviews. We may also collect information from your medical record. We will only collect information that is needed for the research. This information is described in the attached consent form. For you to be in this research, we need your permission to collect and share this information.

We will share your health information with people at the hospital who help with the research. We may share your information with other researchers outside of the hospital. We may also share your information with people outside of the hospital who are in charge of the research, pay for or work with us on the research. Some of these people make sure we do the research properly. The "confidentiality" section of the consent form says who these people are. Some of these people may share your health information with someone else. If they do, the same laws that the hospital must obey may not protect your information.

If you sign this form, we will collect your health information until the end of the research. We may collect some information from your medical records even after your direct participation in the research project ends. We will keep all the information forever, in case we need to look at it again. We will protect the information and keep it confidential.

Your information may also be useful for other studies. We can only use your information again if a special committee in the hospital gives us permission. This committee may ask us to talk to you again before doing the research. But the committee may also let us do the research without talking to you again if we keep your health information private.

If you sign this form, you are giving us permission to collect, use, and share your health information. You do not need to sign this form. If you decide not to sign this form, you cannot be in the research study. You need to sign this form and the attached consent form if you want to be in the research study. We cannot do the research if we cannot collect, use, and share your health information.

If you change your mind later and do not want us to collect, use, or share your health information, you need to send a letter to the researcher listed on the attached consent form. The letter needs to say that you have changed your mind and do not want this authorization form to be good anymore. Until we get such a letter, we will continue to do the things you said we could in this form. You may also need to leave the research study if we cannot collect any more health information. We may still use the information we have already collected. We need to know what happens to everyone who starts a research study, not just those people who stay in it.

Any questions? Please ask the researcher. You can also call (000) 555-5555 with questions about the research use of your health information. The researcher will give you a signed copy of this form.

SIGNATURE, DATE, AND IDENTITY OF PERSON SIGNING

The health information about _____ can be collected and used by the researchers and staff for the research study described in this form and the attached consent form.

Signature: _____ Date:_____

Print name: _____ Relation: _____

Note: The size and style of the type have been altered for this reproduction. The actual size and typeface should be 12 pt. Times Roman

Source: Developed as a proposed draft by Robert M. Nelson, MD, PhD, Associate Professor of Anesthesia and Pediatrics, Children's Hospital of Philadelphia and the University of Pennsylvania.

Authorization Must-Haves

- A description of the protected health information (PHI) to be used or disclosed
- The names of those who could request to see PHI
- The names of those who could grant access to PHI
- A description of why the information is being viewed
- Authorization expiration date
- Signature and date form signed

Also include:

- A statement that tells the individual that he or she may revoke authorization at any time
- A statement that explains whether eligibility to participate in the trial is dependent on the participant agreeing to sign an authorization form
- A statement of the potential risk of having private health information disclosed

Source: Mark Hochhauser, PhD, Golden Valley, MN.

document looks could play an important part in its readability, he says.

"Document design is a crucial part of readability," he says. "Take a look at a 'brief summary' of a direct-to-consumer drug ad in magazines or newspapers. Very often, it's a dense block of text in tiny print. It wouldn't matter if it were written at a sixth-grade reading level, the design makes it illegible and too hard to read.

"Document designers will tell you that the amount of white space in margins and between paragraphs, the size of the font, the number of fonts, the use of illustrations, highlighted text or text in boxes, etc., can make a big difference in a document's appeal to the reader. Most HIPAA privacy notices are not designed, just typed," says Hochhauser.

"Someone told me that one health care organization got their HIPAA notice down to about three pages by simply reducing the font size. Nothing like making readers squint to read about their privacy rights," he says.

Baby steps

Given that privacy notices should contain nearly 30 elements — everything from who will see protected health information (PHI) to instructions on revoking an authorization, a layered approach may be most effective.

"In 2001, financial privacy notices were mandated. They contained nine elements and were heavily criticized as being legalistic and not user-friendly," says **Lisa Sotto**, JD, a privacy regulatory specialist in the New York City office of Hunton & Williams.

"HIPAA notices must contain even more elements. In response to consumer dissatisfaction with the readability of many privacy notice, we came up with the concept of layered notices," she explains.

The layered approach includes a brief overview — termed highlights by Hunton & Williams — accompanied by a longer, more detailed explanation of patient rights under HIPAA.

Hochhauser also supports the layered approach and designed a one-page summary that could be accompanied by the longer notice.

"Less information equals more understanding," he says. ■

(Editor's note: We've included a sample HIPAA authorization form on ***p. 9.*** *It is written on a seventh-grade level.)*

Informed consent goes beyond a signed form

The process is equally important

At first glance, developing a template for an informed consent form seems like a simple thing.

After all, the elements required to be included in a consent form have not changed much since they were first codified 25 years ago.

But ensuring consent forms accomplish those elements has proven tricky for researchers time and again, sometimes at a high price to studies and participants.

Federal regulations require that subjects must be provided certain information — that the study involves research and what the research is for; foreseeable risks and benefits to the participant; alternative procedures that might be more advantageous to the participant; the participant's rights to confidentiality; and the patient's right to refuse to participate or to discontinue participation.

"What the statutes provide is a basic guideline

for what needs to be in the form," says **LaDale George,** JD, a Chicago attorney specializing in health care law. "The guideline is set up on the premise that if you have these elements [in the form], then communication will have occurred. That's not necessarily the case."

A consent form might fully describe the research and its risks and benefits, but be understandable only to a participant who has a college degree in a scientific field, or only to patients who speak English. A form might contain the necessary wording and be understandable to a potential subject, but cultural or custom differences with the person presenting the consent form might prevent him or her from agreeing to participate.

Is form appropriate for special populations?

In addition to language and cultural considerations, the informed consent process must be applicable and appropriate to the study and to the population — consent forms for pediatric studies, those involving people who are mentally disabled, and those that involve prison or institutionalized populations, for example, all require special handling, language, and consideration.

"The three main elements of informed consent are full disclosure, adequate comprehension, and voluntary choice," says **Barbara LoDico**, CIP, executive director of human subjects protection at University of Medicine & Dentistry of New Jersey/Newark.

"But for subjects to understand the research and knowledgeably and voluntarily decide whether or not to participate is going to depend on whether the consent form is such that the population you're dealing with can understand it," she adds.

Institutional review boards (IRBs) and health care legal specialists stress that informed consent is not a form, but a process, and while the core elements have not changed, approaches to making the process work better for a wide variety of studies and subjects have changed.

Sarah Hutchinson, with the University of Minnesota's Research Subjects Protection Program, describes some sections of her IRB's informed consent template that recently were revised to help investigators design consent forms that are more understandable to potential participants.

"What we tried to do is offer more explanation at the onset [for investigators drawing up consent forms], in hopes that we could bypass problems that would result later," she says.

One area that required some redesign was the Minnesota IRB's recommendations regarding language dealing with the storage and use of DNA samples.

"Technology in that area has really evolved in recent years, so the presence of that language in consent forms has been ramped up," Hutchinson says. "We feel that investigators need to make people aware of the ramifications of storing their DNA for future use."

Anticipating current and future issues that might arise from clinical trials makes frequent reevaluation of consent forms a good idea, Hutchinson points out.

According to George, there are some elements of a consent form that have historically proven troublesome, and they are ones that bear close scrutiny when a template is designed.

"Risk and benefits, hands down, are where investigators go wrong," he says. "It needs to be clearly stated if there is a therapeutic benefit to the participant."

As examples, he points out studies at Johns Hopkins University and Penn State University that paid large monetary settlements after it was determined that they failed to disclose that study participants would receive no therapeutic benefits.

"You don't neglect to mention that there are no benefits, and then shortchange on revealing the known and foreseeable risks involved," George states. "That is the standard that investigations must meet in their consent forms."

Costs incurred by patients is another area in which studies sometimes fall short in fully informing their subjects.

"If the patient gets sick from the study or test article and needs hospitalization or therapy, who will pay for that? Some insurance won't cover treatment for adverse effects, while certain sponsors will tell investigators that they will cover the costs of any follow-up care that is required as a result of the subject's participation, and that needs to be clearly set forth," George says.

And finally, while the core requirements haven't

COMING IN FUTURE MONTHS

■ Clinical trial budgeting ■ Monitoring do's and don'ts ■ Research and prisoners ■ Accreditation is coming

changed, the U.S. Department of Health and Human Services (HHS) has issued a draft guideline seeking more disclosure of financial relationships between institutions/investigators and the companies sponsoring research. HHS does not mandate this disclosure, but if IRBs adopt the requirement, investigators are required to put the disclosures in their consent forms. ■

CE/CME objectives

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

- review pertinent regulatory mandates;
- develop practical clinical trial oversight strategies;
- review best practices shared by facilities that successfully conduct clinical trials. ■

CE/CME *questions*

Physicians and nurses participate in this medical education program by reading the issue, using the provided references for further research, and studying the questions at the end of the issue.

Participants should select what they believe to be the correct answers, then refer to the list of correct answers to test their knowledge. To clarify confusion surrounding any questions answered incorrectly, please consult the source material.

After completing this activity at the end of each semester, you must complete the evaluation form provided and return it in the reply envelope provided to receive a certificate of completion. When your evaluation is received, a certificate will be mailed to you. ■

1. Clinical research coordinators should be able to:
   A. coordinate trials in accordance with established protocols, FDA regulations, institutional policies, and ethical clinical practice.
   B. determine patients' clinical protocol eligibility.
   C. analyze and evaluate clinical data.
   D. all of the above

2. Training should include:
   A. ethics.
   B. IRB requirements.
   C. good clinical practices.
   D. all of the above

3. According to readability expert Mark Hochhauser, privacy notices should be written:
   A. in plain language.
   B. at a seventh- to ninth-grade level.
   C. at first-year college level.
   D. none of the above

4. Informed consent is accomplished once the participant signs the consent form.
   A. true
   B. false

Answer Key: 1. D ; 2. D; 3. A; 4. B