



Are parents willing to allow children to participate in clinical research?

Studies show support for research, even when child won't benefit

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To achieve success in pediatric research, investigators need to reach and convince one vital group of people — parents, who must decide whether to expose their children to the inconveniences and even potential risk of research participation.

Two recent studies have provided some insight into attitudes of parents toward their children's participation in research. The findings have a common theme: While some parents are reluctant, there is a substantial group of parents who would give consent for their children — if only anyone would ask them.^{1,2}

"We were surprised that 92% of parents said they'd never been asked about participating in research involving children," says **Matthew M. Davis, MD, MAPP**, associate professor of pediatrics and assistant professor of internal medicine and public policy at the University of Michigan in Ann Arbor and director of the C.S. Mott Children's Hospital National Poll on Children's Health.

"That number to us suggests many missed opportunities for the research community to reach out to parents and children with the potential to participate in meaningful research regarding children's health."

He and **David Wendler, PhD**, head of the unit on vulnerable populations in the department of clinical bioethics at the National Institutes of Health, Bethesda, MD, say there are steps IRBs can take that would help ensure families get the information they need to decide whether to allow their children to participate in clinical studies.

"I think the take-home message for IRBs is that parents and kids are willing to be in this sort of research — not all of them, but the data suggest that a lot of them are willing to be, particularly when it's an important study," Wendler says. "Even if it's not going to help them personally, they want to contribute to an important project. So it's important for IRBs and for investigators to inform parents of that, without exploiting that possibility."

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Polling parents

In December, the C.S. Mott Children's Hospital called more than 2,100 randomly selected adults to ask them about research participation. They completed a survey asking them whether they or their children ever had participated in research,

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Editorial Questions

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and whether they would allow their children to do so.¹

Ten percent of parents reported having been enrolled in research themselves, while 4% said their children had been in a medical study.

Parents were asked whether they would allow their child to participate in a study involving a new medication that previously had been found to be safe in adults. Thirty percent said they would.

Asked about more specific research scenarios, 25% percent of parents would allow their children to participate in a study as a healthy volunteer, as long as the risks were small, and 36% would allow their children to be in a study if the child had the disease being studied.

Davis says he finds these to be promising statistics — particularly the number of parents willing to let their children test drugs previously shown to be safe in adults.

"That is a huge part of pediatric research," he says. "That means we have a very large number of families out there who might participate if only they were asked. The question is, what's stopping us from asking?"

He says part of the answer may lie in insufficient funding for pediatric research, which C.S. Mott and other children's hospitals are seeking to rectify by supporting the Pediatric Research Establishment Act, currently before Congress. The bill would increase funding for cutting-edge pediatric research.

"Another possibility is that we need to improve the systems through which we try to recruit families to research," he says.

Davis says IRBs can contribute to that system by helping researchers understand the factors that are more likely to encourage or discourage parents from participating. Some of those factors were identified in the C.S. Mott survey.

Reasons parents might choose to include their children in a study were:

- If the risk of harm were small (42%);
- If the disease being studied ran in their family (32%);
- If their doctor encouraged participation (30%);
- If the research would help other children (27%); and
- If the child received payment (17%).

Some reasons they might decline to allow their children to participate were:

- Too high a chance for harm (73%);
- Concern about their child being used as a "guinea pig" (60%);

- A belief it was “inappropriate” for their child to participate (41%);
- If their child’s doctor wasn’t directly involved (38%); and
- If the disease being studied didn’t affect their child (36%).

Davis says IRBs can encourage investigators to address those parental concerns during the recruitment process.

“I think it can be favorable for IRBs to advise investigators about these common stumbling blocks for parents,” he says.

Davis suggests that IRBs also can be involved in efforts to broaden the appeal to families to become involved in research, while ensuring that such efforts are done in an appropriate way.

“I don’t mean to say that IRBs are going to start advertising for research, but I do mean that there is a way to encourage families to consider research who may not have considered it before,” he says.

Research without benefits

Wendler’s group looked in more detail at a very specific type of pediatric research — studies in which children did not stand to potentially benefit clinically.²

He says these types of studies can make IRBs and even investigators very squeamish.

“There are a lot of people reluctant to approve them,” he says. “I know a lot of people who are very reluctant to conduct them. Even pediatric investigators I talk to are nervous about it. They’re not sure if what they are doing is acceptable or ethical.”

While many children are enrolled in non-beneficial research, he says studies show that people often don’t understand the difference between clinical care and clinical research, and so may not realize a study has no potential for benefit to their child.

Wendler’s goal was to see if parents and children were willing to be involved in non-beneficial studies in principle.

His team surveyed 81 pairs of parents and children already involved in clinical care or in treatment trials for asthma or cancer, asking whether they would be willing to participate in various hypothetical clinical studies:

- When asked about a study with no benefit to the patient and posing a risk of headache, 71% of children and 72% of parents would agree to the child’s participation.

- For a non-beneficial study that posed a small chance of a broken leg, 43% of children and 24% of parents would agree.

- When asked about a trial that posed a one-in-a-million chance of dying, 42% of children and 18% of parents were willing to let the child participate.

Wendler’s group also asked children and parents whether they would be more willing to participate in non-beneficial research or in a charitable activity. More than a third of the children and more than half of the parents were equally willing to allow either activity.

He says federal regulations base their definitions of risks to children on activities they engage in as part of their daily lives. He thinks charitable activities are a more natural comparison and wanted to see how people perceived the two in a side-by-side comparison.

“Surprisingly, the children who were in research were more willing to help others by being in research, rather than by participating in a charitable activity,” Wendler says. “When we asked them why, some would say, ‘It won’t help me but you can help more people by being in research. You can help kids with diseases and that’s what I care about because I have a disease and I appreciate that.’ You got the kind of responses that suggested that they really understand.”

Assessing risks

The study also revealed the difficulty many people have in accurately comparing potential risks, Wendler says.

While only 18% of parents would allow their child to enroll in a non-beneficial study that posed a one-in-a-million chance of dying, 93% would allow their child to participate in a similar study described as having “the same risks as riding in a car.”

Wendler notes that the risk of death in many car trips is more than one in a million.

“At least for these parents, wording that question that way leads them to prefer the more risky to the less risky activity just because of the way it’s worded,” he says. “I think it really does raise an interesting question about what’s the right way to present this information to get people to make decisions that are reasonable for them.”

He says IRBs need to be aware of how changes in the way data are presented may change people’s perception of risk involved.

“Just being sensitive to the way the risks get described can have an enormous impact on the decisions parents and kids are going to make,” he says. “That’s not to say that I know right now what the right way to do it is. But at least it’s good for them to be sensitive to that possibility and think about it.”

Wendler says studies such as his own and the C.S. Mott poll, which deal in hypothetical situations and not the particulars of a real research decision, are necessarily limited.

“Those questions are very different than the decision that a parent faces when they decide whether or not to enroll their kids in an actual study,” he says. “In that case, you’ve got a nurse or a doctor who’s sitting down with you and asking you to do it and I think that changes it.”

But he says he likes the idea of such polls, which can help achieve more of a national consensus on research.

“Right now, on the one hand, we want to protect the individual kid, and are very reluctant to do this sort of research,” he says. “On the other hand, we want to improve clinical care for kids, which means we have to do this kind of research. I think we need more discussion and agreement on how to balance those two vital considerations in the right way.” ■

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Implementation research raises unique issues

Studies pose issues of who is the research subject

IRBs ordinarily are concerned with studies that test a specific drug or intervention on patients, students, or other end-users of health care services.

But sometimes the subjects of a study aren’t those end-users at all, but rather providers such as physicians, nurses, or teachers. And the study doesn’t test whether a drug or intervention works, but rather how best to implement it.

Such studies, known as implementation

research, can raise confusing questions for IRB review, says **Catarina Kiefe**, PhD, MD, a professor of medicine and biostatistics at the University of Alabama at Birmingham.

“IRBs hardly ever understand it,” Kiefe says. “The IRB regulatory process, by and large, was designed to protect patients, as it should be. Patients in traditional clinical research are frequently subjected to things that could be dangerous — invasive procedures or medications with potentially harmful side effects.

“When you’re talking about implementation research, that’s not the arena that you’re in,” she says. “You know that the intervention works, you’re not experimenting on the patients, really. You’re experimenting on the providers.”

She describes implementation research as one step in the larger process of translational research — using findings generated in one setting and translating them for use in different settings. Along that continuum, an ordinary clinical trial would be the first step.

“Even once you have proven that a certain medication works in the ideal setting of a clinical trial, A) it doesn’t necessarily get taken up in practice by clinicians, and B) sometimes it works very differently in the real world compared to the ivory-tower atmosphere of the traditional clinical trial,” Kiefe says. “The work that goes from knowing that those interventions — medications or procedures or hardware — can work to actually getting them used and used appropriately in the real world is what’s called implementation research.”

An example of an implementation study might be one looking at the use of aspirin with patients suffering the first signs of a heart attack. Since previous studies already have shown that aspirin works to prevent heart attack, the implementation researcher would be testing ways to ensure that health care providers administer it promptly when needed.

Kiefe says one of the challenges of implementation research is that it often is conducted across multiple sites, such as individual physicians’ practices, and requires review by many different IRBs. Some might give the study expedited review, while others require the full board to review it.

“It’s one of the difficulties and challenging aspects of doing this kind of research,” she says. “Each IRB will have different requirements.”

Because the process and subjects being studied are different from more traditional studies, Kiefe

says IRBs can get hung up on issues that confuse implementation research and other types of research.

Patients who aren't subjects

In many implementation studies, patients aren't the ones being studied — the investigator is seeing how a clinician uses a drug or intervention that already has been proven to be safe and effective.

Patients often don't have to sign informed consent documents, since there is no experimental intervention. Kiefe says IRBs often have a hard time understanding this.

"It's an area of disagreement between investigators and IRBs," she says. "It is really very individual IRB-dependent. Some IRBs can be educated to understand the difference and some simply will refuse to say there's a difference and they will insist on treating everything as if we were talking about an invasive procedure for a patient."

Complicating the issue is the fact that sometimes, patients are included as subjects in implementation studies; the investigator may look at their outcomes or ask them to provide feedback, says **Sandra Naoom**, MSPH, associate director and founding member of the National Implementation Research Network at the University of South Florida in Tampa.

The network provides technical and consulting services for institutions and investigators who conduct implementation studies.

Naoom cites an example of a study about teen dating violence currently being funded by the Centers for Disease Control and Prevention (CDC). She says the CDC wanted to look at the effectiveness of educational programs addressing the issue. One of their measures was how faithfully teachers conducting the program adhered to the lesson plan that had been developed for it.

"So really the target of the study is the teachers who are delivering that intervention," she says. "But as part of our measure of fidelity, we've also asked students to tell us how well the teacher is delivering the intervention."

She says investigators also will look at the outcomes for teens exposed to the program. Because some of those questions involve delicate issues of teenage sex, their parents had to give consent for them to be questioned, Naoom says.

"This CDC study is unique in that lots of stud-

ies haven't really looked at asking the person receiving the services whether the person who is delivering those services has delivered them properly," she says.

Differing risks

For providers who are the usual subjects of implementation research, the chief risk is loss of privacy, Kiefe says.

She says clinicians may be concerned about the potential for lawsuits, so investigators can obtain certificates of confidentiality, which protect the data in the study from the threat of subpoena or court order.

"The risk [to providers] is a real risk and it needs to be addressed, but it's a very different risk from putting something in your body that could kill you," Kiefe says. "That difference in risk is not appreciated usually by the IRB."

Because the interventions being studied already have been proven safe and effective, Kiefe says, the risk to patients is minimal. For that reason, she believes implementation research should be subject to a different set of rules than more traditional clinical research.

"It's not just implementation research, but other kinds of epidemiological observational research that should have a different set of rules governing them," she says. "In that kind of research — what one might call minimal risk research — the type of regulations observed should be different than the type of regulations of a chemotherapy trial or an invasive procedure trial."

She doesn't argue that such research should be exempt from review, saying investigators should have to make the case that the study is minimal risk.

While Naoom agrees that many implementation studies bear little risk to patients involved, she does offer a caveat. Implementation studies are based on existing research that shows a medication or intervention is successful in a particular population or setting. Moving the medication or intervention to a different population or setting may entail additional risk to the patients — a point that IRBs should consider in their review.

"In lots of cases, I interviewed developers of evidence-based programs and practices, and they talk about people using their programs and practices and making slight adaptations to them," Naoom says.

While it may be difficult for an IRB to know if

the core components of the original research have been changed substantially, Naoom says members can ask whether the investigator is working with the original developer of the evidence-based program. The program developer who did the original research would know best what parts of the intervention should or should not be changed, she says.

“If someone implementing this intervention is going to use it with a different target population than it was tested for, I would want to know, as part of an IRB, whether they’re working with the program developer, who knows the program well enough to know [if the changes create additional risk],” Naoom says. ■

FDA briefly suspends IRB’s ability to do expedited reviews

Restrictions lifted after company changes SOPs

The FDA briefly suspended the ability of an independent IRB to conduct expedited reviews after raising concerns over the conduct of one such review.

Coast IRB, a Colorado Springs, CO-based IRB, was unable to conduct expedited reviews for a little more than two months after being issued a warning letter by the FDA. The company’s ability to conduct expedited reviews was reinstated in May, after Coast made changes to its standard operating procedures for expedited reviews.

The initial FDA warning letter was issued March 11 following an inspection of the company last year. The letter states that Coast did not follow FDA regulations in its approval of a recruitment advertisement for a Phase 1 multicenter clinical trial.

The FDA warning letter states that Coast’s IRB had met three times to consider the advertisement, first approving the ad with changes, then disapproving the sponsor’s resubmitted ad on the grounds that it was coercive. The warning letter states that after the IRB’s decision, the then-chief executive officer appointed a new member to the board and instructed him to conduct an expedited review of the advertisement.

The warning letter states that the expedited review of the ad was inappropriate, since the new member lacked the necessary experience to

carry out an expedited review and had not been designated by the IRB chairperson. In addition, the warning letter states that the advertisement did not qualify for expedited review under federal regulations, and that Coast did not follow written procedures for keeping IRB members advised about the expedited review.

On April 22 Coast sent a response to the FDA, naming **Gary Smith** as the new president and CEO of the company. In that letter, Smith also details a number of changes to Coast IRB’s expedited review procedures:

- clarifying that such reviews only will be carried out for studies involving no more than minimal risk or to make minor changes to previously approved studies, in accordance with federal regulations;
- restating that only the IRB chairperson or an experienced reviewer designated by the chairperson can carry out expedited reviews;
- explicitly prohibiting expedited review of matters that previously had been disapproved or approved with changes by the full IRB; and
- better communication with IRB members about expedited reviews and improved minute-taking at IRB meetings.

The FDA responded to these changes May 21 by removing the suspension of Coast’s ability to conduct expedited review.

Smith says the company is continuing to improve its processes and has applied for accreditation with the Association for the Accreditation of Human Research Protection Programs. ■

Legal compliance office and IRB work together to better protect subjects

Office relies on not-for-cause audits

Research institutions and officials increasingly are finding that extra layers of oversight are better than too few. While IRBs once were the only organizations to oversee human subjects protection of research participants, now there are additional committees and offices assisting with this task.

At the University of Michigan in Ann Arbor, there’s a relatively new office of human research compliance review, which adds a fresh twist to human subjects research oversight. The new

office conducts not-for-cause audits of research studies.

"Compliance is handled in a lot of different ways," notes **Ronald F. Maio**, DO, MS, director of the office of human research compliance review at the University of Michigan. Maio also is a professor in the department of emergency medicine.

For instance, the department of the office of the vice president for research is ultimately in charge of all IRBs on campus, and all for-cause audits are conducted out of that office, Maio says.

"We have in any given time, including studies with student principal investigators, 5,000 open protocols," Maio says. "And that's just across Ann Arbor campuses."

The new office of human research compliance review is specifically charged with the role of evaluating risk from the human subjects research perspective.

"Our focus is on looking at investigators and studies, but we also have the authority to look at IRBs and ancillary committees, like the biosafety and investigational drug service committee," Maio says. "One of the main functions of the office, which is really unique and different from what the institution has done in the past is this idea of doing not-for-cause regulatory reviews."

Maio says he prefers not to use the term "monitoring" to describe the reviews. The office's not-for-cause reviews are based on the four pillars of compliance review: education, outreach, knowledge generation, and leadership.

"But the bulk of our work and the biggest focus is on compliance review, which has a big educational component to it," Maio explains.

It's more important in today's research climate for institutions to add these extra layers of oversight because the bar has gone up with regard to society's and the federal government's expectations about human subjects research protection, Maio says.

"Also, the research we're doing, particularly in the biomedical sciences, is becoming more and more complex," he adds. "And there are more challenging ethical and regulatory issues we have to address."

These factors are compounded by the explosion of interdisciplinary work that makes studies more complex, Maio says.

"Institutions have to hold themselves accountable to prevent bad things from happening," he says.

Maio chaired a campus-wide task force that developed a plan for conducting not-for-cause reviews of studies.

"We hoped to identify research issues and, essentially, prevent bad things from happening," Maio says. "We wanted to identify them before they got out of hand and provide education to investigators as we do the review."

Another part of it is to acknowledge investigators who are doing a good job and highlight their methods and practices so that others might learn better ways of conducting human subjects research, Maio adds.

"One thing we emphasize to investigators is we really feel we're partners and not the police," he says. "Our main focus is on how we can help the investigator do the safest, most ethical research and do it in a very efficient way."

Reviewers see themselves as a value-added service to the research enterprise and not in the role of punishing investigators who make mistakes, Maio says.

"Although, an investigator could have serious consequences if we go in there and identify a problem," he adds.

Also, the office is independent from the IRBs despite Maio and staff having a long history of working on and with them.

"When we're doing reviews, there is a lot of communication between us and the IRBs because we want to make sure we're not giving investigators mixed messages," Maio says.

As the office completes its first year of not-for-cause reviews, there remain some issues to resolve.

"One of the challenges is trying to figure out how many reviews you should be doing, and we're in the process of talking with peer institutions around the country to develop benchmarks," Maio adds. "But it's very challenging."

Secondly, the office needs to develop a way of emulating best performing investigators and maintaining transparency in the review selection process, he says.

"A substantial minority of investigators on campus think this has a negative connotation," he explains. "As much as we tell them that we're doing this in an unbiased selection process, they still have the idea that if they're reviewed then something is wrong."

Here is how the not-for-cause reviews work:

- **Studies are selected randomly.**

"We select certain categories of research, and within those categories we randomly select

certain studies," Maio says. "In a discussion with the advisory committee, we get a sense of what are the reviews we want to do."

Once the studies are selected, they're placed in a random order and letters are sent to investigators in batches to let them know there will be a not-for-cause review, he says.

"We send an e-mail to the investigator and IRB of record and the research associate at the school where the investigator works," he adds.

"Initially, we don't have a lot of contact with the IRB other than telling them what's going on."

- **Conduct review in phases.**

"The review is a two-phase process," Maio says. "First, we talk with the investigator about the study, and the investigator can have anyone else there, such as research staff or the dean."

In the second phase, after the initial interview with the investigator and staff, the reviewer will begin the research record review.

Principal investigators need not be present, but someone from the study team should be available when needed to help the reviewer obtain access to records, Maio notes.

"Then we write a report of observations, and we send a draft report to the investigator to see if he has any issues relative to the facts," Maio says. "We might say, 'We reviewed 30 subject records,' and he might say, 'You reviewed 35,' so it's just to correct anything having to do with facts."

The reviews, including meeting with PIs, reviewing charts, and drafting a report, take from 20 to more than 30 hours each, and about 60 of these can be done in one year's time, Maio says.

- **Share findings with IRB.**

"We also let the IRB see a copy of this to make sure that if we find things they don't have any concerns," Maio says.

And if the reviewer finds problems during the review, the IRB is notified.

"There is a constant communication with the IRB because we want to make certain we don't send mixed messages to the investigator," Maio says. "We will make suggestions for changes, but we're careful to make sure we don't confuse investigators, so we'll often discuss our recommendations with the IRB first."

When a reviewer believes corrective action is required, the reviewer will talk with the principal investigator and discuss the problems and options for correcting them.

"But before they start to correct the problem, we'll be in contact with the IRB to see what the IRB's take on this is," Maio says. "If there are any

findings, we'll send in a report of observations, listing some areas where we recommend some changes be made, and the investigator, in turn, will give us a corrective action plan."

The key is to keep the relationship collaborative between the review office and the IRB, he notes.

"There are times when we have differences of opinion with the IRB, and we need to discuss this because, ultimately, the IRB has a final word on things," Maio says.

- **Take one of three courses of action.**

After a not-for-cause review in which there are findings, one of three different actions will be taken. Maio lists these as follows:

1. "If we find anything serious and continuing, we immediately notify the investigator and IRB of record and the vice president of research," Maio says.

2. "If we find things at variance to regulations, but not serious and continuing, then we work with the principal investigator and IRB about the best way to correct these," Maio explains. "We try not to have the PI immediately make a correction before we've reviewed the whole study and talked with the IRB because we don't want them to have to do more than they have to do or to have to do it all over again."

3. Sometimes a reviewer will find that an investigator is doing things that meet regulatory compliance guidelines, but which might be done more efficiently or rigorously, Maio says.

"We'll make suggestions to investigators about this, but it doesn't reach the level of having to notify the IRB," Maio says.

So far the not-for-cause reviews and new oversight layer has worked out well for all involved, Maio says.

"In general, people really like it and feel very supportive," he says. "But there's always the concern that what we're doing is transparent." ■

Improve informed consent: Use teach-back to catch language problems

Expert offers suggestions to IRBs

One of the most important ways IRBs can improve the informed consent process is by encouraging investigators to confirm

comprehension for their potential subjects, an expert suggests.

“A consistent trend across many studies is a shockingly high rate of potential subjects who don’t understand key components of the research they’re participating in,” says **Michael Paasche-Orlow**, MD, MA, MPH, an assistant professor at Boston University School of Medicine. Paasche-Orlow has conducted research about the informed consent process.

For instance, research participants might understand the potential benefits and risks of a study if those are well-presented. But an informed consent form that includes boilerplate language about therapeutic misconception does not guarantee that subjects will understand the concept, Paasche-Orlow says.

“Similarly, using an informed consent form that includes language about conflicts of interest doesn’t mean potential subjects will understand what conflicts of interest are,” he adds.

Another common research term that is difficult for research participants to grasp is randomization.

“Potential subjects frequently will say things like, ‘Yeah, well I know my doctor will give me the real stuff,’” Paasche-Orlow says. “Or they’ll make comments, when you ask them in studies about comprehension that reveal they didn’t really understand it.”

One of the areas that people most often fail to understand involves the section that describes compensation for potential injury, he notes.

“I did a study that looked at the complexity of language and boilerplate sections and found that the most complicated subsection was on research-related injury,” Paasche-Orlow says.

“We did some qualitative work where we presented different consent forms to subjects and asked them to talk about what these things meant,” he recalls. “And even if the language was pretty clear, we’d often find that people kind of discounted it.”

For example, a potential subject would comment, “Of course if I was injured they’d pay for it because why would I get stuck with the bill?” he says.

And potential participants would make these comments even when the informed consent form clearly said there would be no compensation for injuries, Paasche-Orlow adds.

“What this means to me is it would be cynical to not do our best with the language and the informed consent forms,” he says. “But the forms

themselves clearly cannot be seen as a stand-in for an adequate consent process.”

The key is to develop a process that confirms comprehension, and Paasche-Orlow recommends the teach-back method.

“I say to subjects, ‘Tell me in your own words what would happen if you joined this study,’” he explains. “I have subjects teach back to me information about the protocol.”

The goal is not to have participants remember every detail, but to ensure they fully understand the key points.

“I say things like ‘We’ve talked about a lot today, so tell me in your own words what would happen in this study if you got injured or if you got sick and went to the emergency room. What would happen then?’” Paasche-Orlow says.

“We walk through the process to see what they think would happen, how they would take care of that bill, and what randomization is about,” he says.

The teach-back method also should focus on having participants explain how they can leave a study without compromising the care they receive from the provider, he adds.

Researchers should use the teach-back method for all of the key ethical components of informed consent.

IRBs can help improve the informed consent process by asking investigators of studies that deserve special scrutiny because of a vulnerable population or a higher risk to require a document trail showing participants’ comprehension of informed consent, Paasche-Orlow says.

The person who provides informed consent might even have an informed consent certificate or authorization form that confirms through documentation that he or she reviewed comprehension of specific knowledge targets, he says.

“Another approach is to have an actual test,” he adds. “In both cases, the potential subject should not be enrolled unless he or she can exhibit comprehension.”

In all three methods of confirming comprehension, including teach-back, documentation, and a test, the goal would be to not enroll subjects who provided incorrect answers and did not correct these. “If they give a wrong answer you give them feedback that they have it wrong,” Paasche-Orlow says. “Then you’ll have to confirm that they have it right.”

In a few cases, this won’t work because the potential participant will hang onto the misconception.

It's Paasche-Orlow's view that research participants who have been through a more rigorous informed consent process will be better research participants.

"The better job you do, the fewer dropouts there will be in the study and the fewer disgruntled subjects," he says.

"Some people say that if you do this you'll scare some people away and have a lower enrollment rate," he adds. "But enrollment isn't the only goal: You want to enroll people who actually understand what they've gotten into." ■

Avoid IRB staff burn-out following these tips

Burnout stems from initial passion

When IRB directors are coping with the repercussions of staff burnout, they should keep in mind that burnout typically only happens to people who have a strong passion for their job, an expert notes.

"People burnout because they really care, and you should take that into account," says **Elizabeth Cothran**, MS, CIP, director of the office of research subject protection at Baylor Research Institute in Dallas, TX.

"People who work in human subjects protection typically are very passionate about it," Cothran says. "And it makes sense that they'd be more prone to burnout."

What happens is an employee will become so emotionally attached and involved in her job that it makes it easier to get burned out on some of the tedious, stressful, and mundane tasks that go with the day-to-day work, Cothran explains.

The same passion that might create potential for burnout also could be used to keep employees excited and energized.

From an individual perspective, IRB staff could look for work and tasks within their organizations that would help them expand their skill set and keep them out of a rut, Cothran suggests.

For example, employees could volunteer for committees or to work with patient advocacy groups, which are available in some health care systems, Cothran says.

IRB directors could improve staff satisfaction through employee reward and recognition programs, Cothran adds.

"It's hard work on one hand, but at my institu-

tion we have three different employee recognition events, including a picnic we hold each year," she says. "I always make sure I volunteer to work at one of these each year, even if it's for handing out bottled water and soft drinks in the drink tent."

The point is for managers to show up and see both their own staff and other employees.

"You see different people and realize that you're a part of the overall institution," Cothran says. "This helps you see something different from the day-to-day paperwork."

IRBs and institutions should encourage participation in company events and employee recognition outings by providing managers and staff with time for it, she suggests.

"That's something we encourage here," she says. "It has to be manageable and something an employee can do and still get work done, but I certainly encourage it."

What an institution gives up on staff time will be rewarded in improved staff productivity, satisfaction, and morale, Cothran adds.

Another way to prevent staff burnout is to provide an active training program with expenses covered for staff.

"We have a training program that brings in different experts," Cothran says. "Our IRB staff and other research personnel go to these."

Another strategy for preventing burnout is to encourage staff to look at their job's specific duties and decide which they like best and which they loathe.

"It's a cumbersome and time-consuming process, but it helps people see what it is they do every day," Cothran says. "You look at the tasks and see which are the most frustrating for you, maybe because they're bothersome or redundant or are things you just don't like to do."

Then the employee looks at parts of the job that are rewarding and make her happy or give her a sense of accomplishment, she adds.

Once these tasks are divided according to which elevates the spirit and which defeats the spirit, the point is for the employee and manager to question why the tasks in the negative category are being done.

"Is this step one that truly protects human subjects and plays an important piece in your world? Or is it something that meets a regulatory requirement?" Cothran says. "If not, then is there a good foundation there so that there might be another way to do that task? Or is there a way to make the task not so frustrating?"

Also, managers could ask themselves whether there might be another employee who could take over that particular task because it's on that employee's list of positive job tasks.

For instance, the Baylor Research Institute's office of research subject protection found that filing was an overwhelming task to the coordinator staff, but one administrative assistant loved doing it, Cothran recalls.

"So we looked at how we could get this administrative assistant, who was good at filing, to help us with filing," she says.

The solution was to share the administrative assistant with his main office by having him help out with filing one afternoon a week, Cothran says.

This began as a temporary solution, but when all parties involved saw the benefits — including a higher morale on the part of the administrative assistant who enjoys contributing to the subject protection office — it became a regular arrangement, she adds.

The office once divided work by task with two levels of employees: One level did more of the clerical work, and the other level did more of the administrative work.

Although such a division seemed necessary at the time, Cothran found that it led to one employee being very frustrated and experiencing burnout in her job.

"We decided to redistribute the work by committee so that employees do equal amounts of jobs that are more rewarding, balanced with doing work that has to be done, but is frustrating," Cothran explains. "This improved one employee's frustration."

The other employees also adjusted, and the office began to function more like a team. Although this meant some staff took on more tedious work, the payoff was that the formerly frustrated employee had better morale, which improved everyone's moods, she adds.

The office has had some staff turnover, but the changes have improved morale and reduced the turnover, Cothran notes.

Another strategy the office has employed

has helped keep IRB membership turnover low and has improved investigator satisfaction, she says.

"We set up reasonable, but very aggressive, timelines for processing our paperwork," Cothran says. "We get it moved from step to step so things don't back up and result in investigators calling us."

The office also has built a strong set of policies and procedures and maps for how things should be done, and these are available for all involved in human subjects research to see.

"This makes people aware of how things should operate, and it helps the IRB administrator and committee because they don't have to feel as though they're winging it," Cothran says. ■

CNE/CME Objectives

The CNE/CME objectives for *IRB Advisor* are to help physicians and nurses be able to:

- **establish** clinical trial programs using accepted ethical principles for human subject protection;
- **apply** the mandated regulatory safeguards for patient recruitment, follow-up and reporting of findings for human subject research;
- **comply** with the necessary educational requirements regarding informed consent and human subject research.

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

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

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

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CNE/CME questions

1. In a national poll, what percentage of parents had *never* been asked about their children's possible participation in research?
 - A. 4%
 - B. 15%
 - C. 75%
 - D. 92%
2. Because patients generally are not the subjects of implementation research, they *never* need to give informed consent.
 - A. True
 - B. False
3. What are the four pillars of human subjects research compliance review?
 - A. Education, outreach, knowledge generation, and leadership
 - B. Audit, report, compliance plan, and continued monitoring
 - C. Education, monitoring, spot-check audits, and compliance plan
 - D. None of the above
4. Which of the following is a way to ensure thorough informed consent of research participants?
 - A. Give potential participants a test
 - B. Use teach-back to assess their comprehension and clear up misunderstandings
 - C. Document each step of the informed consent process and present this in an informed consent certification
 - D. All of the above

Answers: 1. (d), 2. (b), 3. (a), 4. (d).