Many quality improvement studies are research needing IRB review

Human subject QI projects may require IRB oversight

The line between quality improvement (QI) activities, which are intended to improve health care within an institution, and true research, which seeks to contribute knowledge to others outside the institution, has always been blurry. But quality experts say it’s getting harder to differentiate between the two, as QI studies become more rigorous and as projects that may have started as internal surveys end up get presented at conferences and written up in papers.

As a result, there may be a significant number of such studies going on at an institution without the IRB’s awareness or review, says Peter Lindenauer, MD, MSc, associate medical director in the division of health care quality at Baystate Medical Center in Springfield, MA.

Lindenauer was lead author of a 2002 survey in the American Journal of Medicine that found significant disparities between what QI officers and IRB chairs believed to be research that required IRB review.1 When asked about various QI scenarios, ranging from internal communications aimed at improving care to a plan to publish results, quality officers were less likely, in most cases, to believe that the project required IRB review.

Even at a single institution, the quality officer and IRB chair had differing ideas about the need for reviewing the proposal.

Lindenauer says he believes the problem likely has worsened in the past few years, thanks to a growth in QI projects and the greater participation of physician leaders who may wish to publish their results.

Jacqueline Byers, PhD, RN, CNA, CPHQ, associate professor of nursing at the University of Central Florida in Orlando, and research editor for the Journal for Healthcare Quality, says she’s seen a noticeable increase in the scientific rigor of articles submitted for her publication.

Often, she says, when she asks for proof of human subjects protection review, the answer comes back: “Well, it’s QI, so we don’t need to go before an IRB.”

“But an investigator can’t determine that,” she says. “There needs to
be some sort of institutional mechanism; and if it’s not the IRB, it needs to be designated to some other body.”

Lindauer says he believes many QI departments and IRBs rely on a mutual “don’t ask, don’t tell” arrangement to avoid hassles for either entity. QI officers may refrain from submitting their proposals to IRBs because they don’t want the projects delayed. And IRBs don’t press them for details of their studies because they worry about the increased workload.

But he adds that IRB review is important for these studies, which may include elements that could put patients at risk.

“What goes under the guise or the umbrella of quality improvement varies tremendously,” Lindauer says. “There are projects that are called quality improvement projects, which are focused on getting more people the standard measure of high-quality care. But you also may have a project where, say, we want to shorten length of stay by 50% because our hospital has to save money. Thinking as an advocate for patients, I would want to have some degree of comfort that it would be safe to shorten a patient’s length of stay.”

Byers, who also serves as co-chair of her university’s IRB, says one of her goals is to educate quality professionals that they should submit their proposals to IRBs, even though most would be considered exempt or gain expedited review.

And she says IRBs need to figure out a practical way of dealing with those submissions, so that it doesn’t overburden the board or stymie QI efforts.

“I think the time to put it on the IRB professionals’ radar screen is now, and to start the dialogue,” Byers says.

**What’s QI; what’s research?**

The Common Rule (45 CFR 46.102.d) defines research as the “systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.”

The key term for assessing a quality improvement project’s status tends to be “generalizable,” say Byers and Lindauer. That is, do those planning the study intend only to disseminate it to their own staff, to let them know the best method of achieving results within their own institution? Or do they perhaps plan to use the information in a journal article, or for a poster at a conference, or even on a billboard to tout the hospital’s accomplishments to the public?

If the answer is the latter, it’s generalizable knowledge and must be reviewed by an IRB, Byers says.

Another important distinction is that research may open patients up to a different standard or method of care, which would make them human subjects and requires review, she says.

“For example, I did a study in a neonatal intensive care unit a few years ago, where we were piloting a different care delivery model so we were changing the standard of care,” she says. “We sent that through IRB, because No. 1, we wanted to disseminate it with posters and
publications, which is clearly generalizable knowledge, but secondly, because we were exposing the infants to a different type of care model.”

Lindenauer adds that an attempt to provide a control group for an intervention — giving it to one unit, but not to another in order to compare results — is another red flag that an IRB should sign off on it.

Byers says the slope between QI and research can be a slippery one.

“As a QI professional, you go into it thinking, this is innocent, I’m only going to audit 30 charts and see how the pain management is being taken care of. And then you say, ‘Well, we seem to have an issue here’; and you go into another study, and then the next thing you know, there’s a nurse executive presenting at a state conference talking about how they solved the pain management problem in their organization,” she says.

Byers says the first example would fit clearly under a QI umbrella, but as you use knowledge from that study for other studies, it all becomes generalizable.

“It’s an extremely, extremely, gray area,” she says.

All the better, Byers says, to overreport to IRBs rather than underreport.

**Reaching out to QI**

Byers says IRBs need to reach out to their QI teams to get a handle on the type of studies they’re doing. Because quality professionals often don’t have the same in-depth knowledge of human subjects regulations that IRBs do, they need to be provided with information to help them figure out when an IRB must review their work.

Checklists containing elements of the federal regulations, similar to those commonly given researchers, can be used to help determine whether a quality officer believes a study is exempt or expedited, Byers says.

“But they still need to submit it,” she says. “The key thing is that the people who are performing the study are not determining its level.”

In order to deal with what could be a significant increase in submissions to the IRB, Byers says an institution can create a subcommittee similar to the privacy boards that mete out HIPAA decisions.

At her institution, a subcommittee with expertise in quality improvement and risk management handles those proposals, and is authorized to designate studies as exempt.

“The IRB doesn’t have to do it all, and the IRB chair doesn’t have to do it all,” she says. “But those people on the subcommittee need to have the same OHRP on-line instruction, all the stuff an IRB member would get.”

Ultimately, Lindenauer says, he’d like to see leaders in the field of human subjects protection and quality improvement work together to hammer out a more standardized approach to deciding how quality improvement studies should be handled.

“Until that happens, there’s going to be huge variations across organizations about how quality improvement is overseen,” he says.

**Reference**


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**Deceiving subjects — What’s an IRB to do?**

**Develop guidelines for researchers**

Deception has long been a tool of investigators conducting social and behavioral research. Subjects agreeing to a study may not know exactly what it is about, in order to elicit unguarded responses. Key information about their tasks in the study may be withheld from them. In some cases, investigators may flatly lie to a subject to test a hypothesis.

Although IRBs may approve studies that include deceptive elements, such research raises serious concerns regarding informed consent and possible risk to subjects.

As they review proposals, IRBs need to ensure that subjects are protected by carefully thinking through the necessity of the deception, and providing for a “debriefing,” or full disclosure to subjects at the end of the experiment, along with a chance for them to withdraw from the study if they choose.

Fred Rhodewalt, PhD, associate dean and professor of psychology at the University of Utah in Salt Lake City, recently worked with the university’s IRB to develop a set of guidelines for researchers who use deception in their work.

He says deceptive research can be carried out with sensitivity and, in fact, often is viewed with satisfaction by participants once they know the
truth. He cites surveys of students, who make up the bulk of the subject pool for campus social-behavioral research.

"On the question of educational value and enjoyment, students think they learn a lot more and enjoy much more the deceptive experiments than the plain dry nondeceptive ones," Rhodewalt says.

That's even true for the most controversial deceptive research — for example, experiments in social conformity conducted at Yale University by Stanley Milgram in the early 1960s, says Bryan Benham, PhD, an assistant professor of philosophy at the University of Utah.

In Milgram's experiments, subjects were ordered to administer what they believed were severe electric shocks to a victim, who was in fact unharmed and only acting as if he were injured. After the experiment, subjects were told of the deception.

When researchers went back later to interview the subjects, "a large number said that even though it was disturbing to find out they could do things like harm people, they found it to be an extremely valuable and life-changing experience," Benham says.

Benham, who has studied the use of deception in research, says the notoriety of those experiments led to a reevaluation of deceptive research. He says many of the experiments conducted during the 1950s and 1960s would never be approved by an IRB today.

However, lesser deceptions are fairly common, particularly in social psychology. Benham says that based on various studies of published research, he would estimate that 40% to 50% of articles in social psychology's leading journals use some form of deception.

The principal defense offered by researchers for deceptive methods is that they are the only way to get truly honest responses from subjects, Benham says.

Rhodewalt says some of his work involves testing subjects and then giving them different types of feedback about how they did. They then are given an opportunity to retake the test and choose the conditions under which they take it. That second offer is deceptive, Rhodewalt says. There never is any intention to re-administer the test; he simply wants to know what conditions the subjects would choose.

But he says many studies employ passive deception, in which the subject is told everything about his participation in a study except the purpose of the study.

"In terms of the procedures, there's nothing deceptive," he says. "You're doing exactly the things you would have done otherwise. It's just the reasons you're being asked to do it — you're not told that."

But Benham contends that any degree of deception raises issues that IRBs should be concerned about. How often is it truly necessary? How should informed consent be handled? And what happens when subjects are finally told the truth about their involvement in the study?

**The impact on informal consent**

Those issues came to the forefront when the University of Utah recently reviewed its practices regarding deception in social-behavioral research, Rhodewalt says. He says some board members suggested that the informed consent documents in those experiments should include boilerplate language warning subjects that they weren't being told everything about the study.

But he and other researchers who use deception in their work argue that that requirement could bias subjects.

"We had to tell them we were deceiving them and then tell them that only if they were the kind of person who didn't mind being deceived, should they go ahead," Rhodewalt says.

As a liaison to the IRB, he instead proposed a protocol based on professional guidelines such as those put forward by the American Psychological Association.

The guidelines allow deception, but restrict it in a number of ways:

- The researcher must explain to the IRB exactly what the deception entails.
- Deception may not be used in studies that are expected to cause physical pain or severe emotional distress.
- The researcher must justify the use of the deception, explaining to the IRB why the research is important enough to warrant it, and why using nondeceptive methods isn't possible.
- The researcher must provide a script for the debriefing session, explaining in detail how subjects will be told about the deception. The researcher also has the obligation of determining whether the subject really understands the deception, regardless of whether he says that he does.
- The subjects all must be given the option of withdrawing from the study and having their data removed.
Rhodewalt says the guidelines comply with federal regulations, which allow informed consent to be waived or altered if the research involved “could not practically be carried out without the waiver or alteration” (45 CFR 46.116.d), and lays out requirements for protecting subjects.

He adds that research he has seen generally supports the idea that what protects subjects best is a good debriefing phase. Rhodewalt says there’s a fairly low incidence of subjects withdrawing from studies during debriefing, and that’s usually when the information elicited was particularly sensitive to the subject.

“If somebody found they were likely to act aggressively toward somebody else in an experiment, for example, that would be an uncomfortable bit of information,” he explains, “but the vast majority do not withdraw.”

While the board ultimately decided not to require disclaimers in the informed consent documents, one member, Leslie Francis, PhD, chair of the philosophy department, says she still believes they could be used without prejudicing subjects.

She says researchers could inform subjects who sign up to be in the pool of research subjects at a university that some of the studies for which they might be recruited may have deceptive elements. That, she says, wouldn’t bias any one particular study.

And because many of the subjects are themselves psychology students, Francis says they need to understand the ethical issues surrounding research and protection of human subjects.

“They’d better well know before they join the psych subject pool that some psych studies sometimes involve not giving full disclosure at the beginning,” she says. “That ought to be part of the discussion of ethics in research and psychology, anyway.”

Benham and Rhodewalt also suggest other possible ways that IRBs and researchers can take extra steps to protect subjects:

**Recruitment.** Benham notes that one of the drawbacks to deceptive studies is that subjects may be recruited who never would have agreed to participate had they known the true purpose of the study.

He says recruitment materials should be designed in such a way that they would not attract a significant number of those subjects. There is a way to test for that possibility: Once subjects are chosen for the study, a group of them are picked at random, told the true details of the study and asked if they still would agree to it.

“If you get a substantial number of people saying yes, then you have good grounds for thinking this is not the type of deception that would change people’s minds,” Benham says.

But he says that because those subjects would no longer be eligible for the study, many researchers consider it to be a waste of the effort required to recruit them.

**Vulnerable subjects.** Benham says using deceptive studies in children, mentally ill patients, or other vulnerable groups can be especially troubling.

“If we were to put children in a circumstance that was wholly constructed — false — they may not be able to distinguish that from reality, even after a debriefing period,” he says. “I think that for people such as children or people who suffer from mental illness, or dementia, deception ought not be used, generally speaking, because we can’t adequately protect them through a debriefing process.”

**Using debriefing to re-establish self-esteem.** Rhodewalt points out that one of the damaging aspects of a deceptive study is that the subjects may end up feeling duped, or gullible. He says it’s possible to structure the debriefing so that it bolsters the subjects’ self-image at least back to the point where it was when the study began.

At the end of his experiments, Rhodewalt asks subjects to tell him whether they suspected that they were being deceived.

“If they say no, we tell them that most people weren’t, that we’ve designed this so that the majority of people think what we say is happening,” Rhodewalt says. “If they say, ‘I knew what you were doing all along,’ we say, ‘Well, you’re pretty perceptive.’

“We added up in my years at Utah; I’ve had between 2,500 and 3,000 research participants, and nobody’s ever complained,” he continues. “So you can do this in a sensitive way, and in a way that people feel like they learned something and that it was worthwhile.”

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**Does records scanning violate patient privacy?**

Some argue it actually protects patients

As technological advancements make it possible to quickly and easily scan large numbers of medical records to conduct research, there is
increasing public concern about the possible intrusions to patient privacy. But careful review by IRBs can ensure that such research can be done ethically and can even provide more stringent protection to patients than previous searches conducted by hand.

“We need to recognize that medical records research has been going on for years and is a staple of medical research,” says P. Pearl O’Rourke, MD, director of human research affairs for Partners HealthCare System in Boston. “All of these computerized systems don’t change the fact that it has been happening. It just changes the ease with which it can be done.”

Researchers have recently announced powerful new systems that can reach deep into millions of medical files to find information about different illnesses. Potentially, such a system could look for trends in family histories, lifestyle behaviors, even genetics, more quickly and easily than ever was possible before.

The principal risk to patients is the potential breach of their privacy, O’Rourke says, and IRBs need to cut through the worry about the technology to focus on exactly what the privacy risk is — whether patients are identifiable, whether the information is particularly sensitive and if patients must be informed of the use or asked permission to have their records included.

**Do you have a subject?**

She says the first question IRBs must ask is whether a particular protocol even has an identifiable human subject. She uses the example of a researcher studying appendectomies wanting to do a computerized search of all such procedures performed on patients who live in a particular ZIP code.

“That would require going to identifiable information, and before a medical records room could give you that information, you as the investigator would have to go to the IRB,” O’Rourke says.

Next, she says, the IRB should deal with the issue of protecting patient privacy. Here, they not only must reference regular informed consent regulations, but also the requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), which has its own requirements for alerting patients to uses of their medical information.

In the example O’Rourke used, regarding appendectomies, she says an IRB might conclude that the potential loss of privacy would entail a minimal risk, and so the need for informed consent could be waived.

But for medical information of a more sensitive nature, that would not necessarily be the case, she says.

“Let’s say you wanted to look at medical records review for drug use or aberrant sexual behavior, something that would be more sensitive,” she says. “That’s where the IRB might say you can’t do it unless you go and get consent from all these people.”

If the IRB were to require it, the investigator would have to notify anyone whose record was being used to ask their permission to include data. In some cases, researchers might consider it to be worth the trouble, particularly if the group involved comprises an easily accessible community of patients, such as people with a specific form of cancer. But in other cases, the investigator might conclude that it would be too difficult to proceed with the research.

O’Rourke says the recent increased use of genetic information, including actual genetic testing of patients, adds a measure of intensity to public concerns about the use of their information. But those types of medical records would almost certainly involve identifiable information, and so would be subject to careful IRB review.

HIPAA adds multiple layers of safeguards to patients whose records might be sought by an investigator:

- **First**, the IRB or some other committee that acts as a privacy board must determine whether patients have to be notified of the disclosure or authorization can be waived.

- **Investigators** are required to use only the minimal necessary information and so must justify every bit of data they intend to collect to the privacy board. If an investigator, for example, wants to look at appendectomies but also at a patient’s psychiatric history, the board would ask him to explain why both are needed for the research.

O’Rourke says that line of questioning isn’t new to IRBs. “IRBs always have looked at that, too,” she says. “They’ve asked, ‘What are the data points you want, why do you want them, etc.?’ So I think that was already going on, but HIPAA formalized it, in a good way.”

HIPAA also requires that investigators carefully document any transaction in which data leave the health system where they were collected. So if an investigator shares data with someone else at another institution, he or she must make a record of it. And the privacy board
will ask the investigator to show that the data will be kept and used in a secure way, so that others without authorization can’t access them.

O’Rourke says institutions that plan on using patients’ records for research must include that intention in the privacy notice that patients sign. But that document doesn’t absolve the institutions of the other HIPAA and informed consent requirements.

“Our privacy notice essentially tells people that if you come to our institution, research is one of our missions and we will use your information for research of which you are unaware,” she says. “But we also tell them that information will not be given out unless it goes before an IRB and is done in an ethical manner.”

**Computer protections**

O’Rourke says the requirements of HIPAA and the recent development of more powerful computing abilities have combined to make the general public much more aware that their records can be viewed by others, and that they can be used in ways they may not have imagined before.

While it causes some patients anxiety, she points out that it’s important to explain the benefits of this kind of research — “It’s how we develop the flu vaccine every year; it’s how we learn about so many cancer-related exposures,” O’Rourke explains.

And the high-speed record scanning capabilities can do those things much faster and more easily. While it exposes more patients to the possibility that their records could be used, it also provides greater opportunities to protect their privacy, if investigators and IRBs know how to take advantage of the technology.

For example, O’Rourke says, a computer program, unlike a human being, can extract needed information without reading the entire file. So in cases where identifiable information is not needed, the computer can search only the data fields that apply, leaving the rest of the information secure.

“The computer also makes it safer from a standpoint of collecting minimum necessary [data],” she says. “You can say, 'I promise all I’m going to look at is the sodium level,' but if you have to do that by looking through medical charts, that’s physically impossible. If it’s computerized, you can just pull out the sodium levels.”

And unlike humans thumbing through files, an investigator running a computerized scan of records leaves a trail showing what was accessed, which can be audited to ensure they’re only collecting the data that’s been authorized.

“If you access a computer database, you leave a record,” O’Rourke says. “We know who you looked at, and can go back and say, ‘Why exactly were you here?’

“On the other hand, going into the medical records room is like going through library stacks,” she says. “How do you know which book they pulled off the shelf? In that way, I think [computerization] helps protect privacy.”

She says IRBs should learn to fine-tune their questions to investigators to take advantages of the privacy protections inherent in computerized scanning.

“The bigger message is to both investigators and to the public: That this is an acceptable way of doing research and has been for many years — if it’s done carefully — with an awful lot of attention to protecting confidentiality.”

**JCAHO, NCQA dissolve accrediting body**

**Effort never caught on among key stakeholders**

With only nine organizations receiving accreditation through its Partnership for Human Research Protection (PHRP), the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) and its partner in the effort, the National Commission on Quality Assurance (NCQA) have jointly decided to dissolve the agency.

“The need for critical improvements in protection for participants in research remains strong,” says Mary Faith Marshall, chair of the PHRP’s board. “Unfortunately, there is not, as yet, enough demand for a rigorous oversight program like the one offered by PHRP from either the public or private sector.”

The PHRP program was established in 2003 to provide a national set of standards on human subjects protections and a voluntary oversight process for institutions conducting research involving volunteers who participate in clinical trials and other research activities.

Institutions receiving federal funding are required to adhere to specific standards and processes for conducting research involving human subjects and submit to the oversight and review of the federal OHRP, but privately
funded research efforts are not covered under the federal regulations.

The PHRP was an effort to standardize the quality of oversight and the protections offered to people volunteering as subjects in clinical trials and other research activities.

The NCQA and JCAHO collaborated on a national set of standards and a voluntary oversight process for institutions seeking national accreditation. The PHRP accreditation program was specifically designed to address issues identified in the 2001 Institute of Medicine report, Preserving Public Trust: Accreditation and Human Research Protection Programs. The standards addressed organization responsibilities, IRB structure and operations; consideration of risks and benefits; and informed consent.

But demand for such a high level of national accountability never materialized among the key players in clinical research, PHRP representatives said.

"Although the Joint Commission and NCQA continue to believe that an in-depth examination of the protections provided for human research subjects participating in clinical trials — such as a comprehensive accreditation review — is one of the best ways to ensure safety, government regulators, pharmaceutical companies and other stakeholders do not yet demand this level of public accountability," the PHRP stated in an announcement of the decision on its web site in August.

However, the PHRP is not the only organization offering national accreditation in this area, says Marjorie Speers, executive director of the Association for the Accreditation of Human Research Protection Programs (AAHRPP) in Washington, DC.


Originally incorporated in Massachusetts by PRIM&R and later incorporated as a nonprofit organization in Maryland in 2001, AAHRPP now offers accreditation to institutions nationwide that conduct or review research with human participants. The AAHRPP accreditation program also uses a voluntary, peer-driven, educational model.

Since its founding, 24 entities representing 84 institutions have received accreditation and more than 200 research organizations currently are in the process, Speers reports. Among the accredited organizations are community hospitals, cancer centers, and teaching hospitals; independent IRBs; research institutes, and universities.

Accreditation for human subject protection programs is new and, as with other accreditation efforts in the past, it will take some time before such standards achieve universal support and buy-in. But progress is being made, she says.

"Industry is showing support for accreditation is a very tangible way. Our accredited organizations report that pharmaceutical companies have pre-approved them for clinical trials and canceled inspections because they were accredited," Speers notes. "As more organizations become accredited, industry's placement of research at accredited sites is sure to grow."

The PHRP will be effectively dissolved as of Nov. 15, with JCAHO and NCQA assuming responsibility for supporting the nine currently accredited organizations through the duration of their three-year accreditation.

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HHS encourages obesity research

A new study released by the Centers for Disease Control and Prevention shows that deaths due to poor diet and physical inactivity rose by 33% over the past decade and soon may overtake tobacco as the leading preventable cause of death.

In an effort to deal with the growing problem of obesity in this country, HHS Secretary Tommy G. Thompson announced a new national education campaign and a new NIH research agenda.

The NIH strategy will intensify research to better understand, prevent and treat obesity through:

1. behavioral and environmental approaches to modifying lifestyle;
pharmacologic, surgical, and other medical approaches;
- breaking the link between obesity and diseases such as Type 2 diabetes, heart disease and some forms of cancer.


Current year NIH funding for obesity research is $400.1 million, up from $378.6 million in fiscal year 2003. The budget request for fiscal year 2005 is $440.3 million, a 10% increase from the current year.

NIH finalized new ethics guidelines

Pulling back slightly from an earlier plan, NIH last week unveiled final conflict of interest regulations on its employees, which turned out to be less restrictive than those first enacted six months ago.

The new restrictions vary, depending on the employee’s role at the public health agency. For example, senior management and others who play roles in research decisions must meet a higher standard of disclosure and divestiture than those who don’t. Such a concession, which is less limiting than rules put in place in February, reflects thinking that NIH employees must be allowed interaction with professional associations, participation in public health activities and genuine teaching opportunities to advance science and keep on the cutting edge of research.

“Our research should be based on scientific evidence that is not influenced by any other factors,” NIH director Elias Zerhouni said during a conference call. “The trust of the public and the ability for us to provide scientific advice that’s untainted is the No. 1 goal of all of our efforts.”

The final rules still prohibit outside consulting by NIH staff to substantially affected organizations, such as pharmaceutical, biotechnology or medical device manufacturing companies, health care providers or insurers and supported research institutions.

But a number of caveats are built into the remainder of the guidelines, based largely on employee status.

All senior employees, a group of about 200 that includes Zerhouni, the heads of each institute and others with decision-making responsibilities, must divest all $15,000-plus holdings per company in organizations that do business with the NIH. That rule also applies to their spouses and minor children. Other employees also could be required to divest if, after review, a potential conflict resulting from their holdings or those of their spouses and minor children would impede their ability to do their government job.

Outside monetary awards will continue to be contingent upon prior approval and be limited to awards that are determined through a pre-screening process. The regulations will bar senior employees from receiving cash components of such awards offered by donors who have matters pending under their official responsibility.

Employees who file either public or confidential financial disclosure reports, and those nonfilers who serve as clinical investigators identified on an NIH clinical study, are required to report their interests in organizations that do business with the NIH, as well as those of their spouse and minor children, and to indicate the amount held in such investments.

Lastly, to facilitate academic and scientific interactions, the final regulations will allow outside activities with professional or scientific organizations, service on data and safety monitoring boards, lectures and scientific grant review, as well as maintaining current provisions that permit NIH scientists to engage in compensated academic outside activities, such as teaching courses at universities, writing general textbooks, performing scientific journal reviews or editing and providing general lectures as part of continuing professional education programs. NIH scientists also can engage in the practice of medicine and other health professions with prior approval and in accordance with existing rules.

Zerhouni stressed that the final guidelines reflect an effort aimed at “our ability to continue to attract and retain the best scientists and staff.”

The regulations were developed by the Department of Health and Human Services, in close collaboration with NIH, and with the concurrence of the Office of Government Ethics, the federal agency that prescribes executive branchwide ethics standards. The rules also follow comments about the interim ethics regulation submitted by NIH staff, the public and scientific organizations.

“We’ve done what we said we would do, and that is that we would listen and reach at the end what is the right way to serve the public,” said Zerhouni. “That’s to have a set of rules that absolutely and positively protect the integrity of the...
agency, while at the same time not imposing burdens that are not necessary to maintain the mission of the agency.”

The NIH is made of 27 institutes and centers and is a component of the U.S. Department of Health and Human Services. ▼

**Congress calls for probe on trial leaks**

News that clinical trial investigators have been leaking study data to Wall Street traders has prompted a congressional call for a Securities and Exchange Commission investigation into the practice, though many who see it as commonplace have written it off as part of the game.

Sen. Chuck Grassley (R-IA), the chairman of the Senate Finance Committee, expressed shock at what allegedly has become a routine method of profiteering for trial investigators and their stock-selling cohorts. The former are paid for their inside scoops, which critics say compromises their confidentiality agreements by giving trends on ongoing studies that lead to early outcome projections, while the latter earn on trades triggered by such tips.

“These biotech stocks are generally cheaply priced and highly speculative,” said Kerry Fields, an associate professor at the University of Southern California’s Marshall School of Business in Los Angeles. “Due to the nature of the stock, it encourages the use of this insider information. It’s the modern gold rush.”

He described a system that has developed in which pressures to achieve top investment results have driven traders to push ethical boundaries in seeking clinical trial disclosures in an effort to forecast stock activity.

Details of the practice initially were published earlier this week by the Seattle Times reported more than two dozen cases in which doctors had provided ongoing drug research data to the Street — a practice know as channel check. While the report noted instances in which doctors are polled directly by securities firms, oftentimes the two parties are linked by way of third-party businesses that set up such relationships. Traders use information gleaned from multiple physicians to triangulate opinions on the prospects of a particular product to get a better handle on a business. Also, the drug companies themselves sometimes put buy- and sell-side analysts in touch with clinical trial investigators.

All sides have defended their actions, noting that such dealings operate outside federal securities regulations because existing laws categorize clinical trial investigators as experts, not insiders. Instead, that definition currently encompasses company directors, officers, employees and controlling shareholders.

“It’s highly unethical,” commented Fields, who frequently comments on business ethics to professional organizations outside the classroom. “Politicians should urge the SEC and state regulators to declare this to be a true breach of fiduciary duties and liability for insider information.”

He argued that experts involved in research and development projects for publicly traded companies should be held to a higher standard, that of an insider. The SEC’s web site labels insider trading as “buying or selling a security, in breach of a fiduciary duty or other relationship of trust and confidence, while in possession of material, nonpublic information about the security. Insider trading violations may also include tipping such information, securities trading by the person tipped and securities trading by those who misappropriate such information.”

In the past, Fields said courts have ruled that experts are not considered insiders to preserve their independent contractor status, an exception that has allowed clinical trial investigators to operate in consultation with traders. But obviously that gray area has become murky.

Fields said it is routine for those who overstep ethical boundaries in the business world to rationalize their actions, claiming that by only providing clues at a certain time in a clinical study, they are not giving absolutes. That justifies the practice in their eyes.

“But in truth,” he said, “it’s a complete dismissal of their ethical obligations, aside from their legal ones.”

And Fields said the problem has rested on the shoulders of such clinical trial investigators, who have chosen to act in favor of taking a few carrots dangled by stock traders.

“Only if we impose civil liability on those experts, with insider trading liability, can we get rid of the problem,” he said.

That could happen, analysts acknowledged, but the financial community would likely adapt to any restrictions. They said fund managers would continue to find a way to forecast good investment decisions for their clients — that’s their business. ▼
Angry jurors hand down big award

In August, a jury handed down the first verdict against Merck & Co. Inc. related to Vioxx, its painkiller pulled from the market in 2004 due to safety concerns. The award was a whopping $235.4 million to plaintiff Carol Ernst.

But what might be more alarming for drug makers than the amount is the attitude of the jurors. Derrick Chizer, a juror in the case, told reporters that the award was a “message” to pharmaceutical firms. “Respect us,” he said.

Ernst herself called the verdict a “wake-up call” for big pharma. It’s been an especially rude awakening for Merck, which faces more than 4,000 cases related to Vioxx and its link to heart attacks. Whitehouse Station, NJ-based Merck plans to appeal, but what kind of shape the company will be in when it all settles out is up for debate.

The disrespect jurors felt highlights just how much trouble the pharmaceutical industry is in. Once considered makers of life-saving and curative drugs, big pharma these days is seen as a collection of cutthroat businesses, ruthlessly chasing their bottom lines at the expense of public safety.

“This is an industry, which, quite frankly, has a poor reputation in the public’s viewpoint,” Peter Claude, a partner at PricewaterhouseCoopers LLP, told BioWorld Today.

PricewaterhouseCoopers of New York City is putting together a series of reports on the public’s impression of big pharma and the life sciences industry. Their first publication, “Recapturing the Vision: Integrity Driven Performance in the Pharmaceutical Industry,” includes a graph by Harris Interactive Survey, which showed that in 1997, nearly 80% of people questioned about pharmaceutical companies thought they were doing a good job serving their customers.

By 2004, that had fallen to slightly more than 40%, placing it well below computer hardware companies and car manufacturers. It still ranked above oil companies and the tobacco industry, though not by much — those industries hovered around 31% approval in 2004.

The angry Merck jurors bring forth memories of the big tobacco verdict in 2000 — an award of $145 billion to members of a class-action suit. Jurors then were seething, too, over an industry that hid safety data in order to better sell its products. But Claude said the analogy between tobacco and pharma is wrong, no matter what the public thinks.

“It’s an [incorrect] reference, because the issues surrounding tobacco have been known for years,” and because smoking is a choice, he said. “With a pharmaceutical product, there’s an assumption, and it’s unfair, that everything taken is safe because it’s been cleared by the FDA.”

But that isn’t the case — all drugs carry side effects, and when a drug is taken by hundreds of thousands of people, those side effects will show up. That doesn’t mean the drug provided no benefit to everyone else, so “any betrayal the public might be thinking is totally unwarranted,” Claude said.

Still, unwarranted or not, a big tobacco-like backlash is “likely to occur,” if pharma doesn’t publicly relate what good it provides, concluded Brian Riewerts, also a partner at PWC.
Physicians, nurses, and others participate in this continuing education program by reading the article, 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.

13. Which of the following is not an example of “generalizable” knowledge that would cause a quality improvement study to be considered research?
A. Using patient survey results on a billboard touting a hospital’s efficiency
B. Using audits of charts to inform nurses in a unit about improving pain management
C. Using a study of computerized reminders to doctors as the basis for a journal article
D. Using different clinical practice guidelines in two different units to compare outcomes

14. According to studies of deceptive research, what is considered the key element to protecting patients?
A. Warning them ahead of time that they won’t know all the details of the study they’re engaging in
B. Designing recruitment materials to avoid attracting people who wouldn’t have agreed to participate if they knew of the deception
C. A thorough debriefing phase, in which the subject is told of the deception and offered a chance to withdraw his or her data
D. None of the above

15. The privacy notice that a patient signs allows his or her medical information to be used for research purposes without IRB review.
A. True B. False

16. HIPAA adds multiple layers of safeguards to patients whose records might be sought by an investigator, including which of the following?
A. The IRB or a privacy board must determine whether patients have to be notified of the disclosure or whether authorization can be waived.
B. Investigators are required to use only the minimal necessary information.
C. Investigators must carefully document any transaction in which data leave the health system where they were collected.
D. All of the above

Answers: 13-B; 14-C; 15-B; 16-D.