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Clinical Trials COMPLIANCE

STRATEGIES FOR MEDICARE BILLING, FDA, AND RESEARCH COMPLIANCE

—INSIDE—

Fraud and abuse

Learn which laws are most commonly violated on p. 4.

Ethical questions

A Chinese fertility trial has raised questions about overseas trials. Learn more on p. 8.

OHRP

Learn more about how IRB responsibilities are changing in the wake of a letter sent by OHRP on p. 9.

Legal issues

Turn to p. 10 to find out how our experts answered your toughest questions.

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Avoid fraud and abuse issues in connection with clinical trials

In 1996, a pharmacologist and a physician were prosecuted in Atlanta for a variety of offenses, including bribery and creating false results in psychiatric drug studies. It was also alleged that the two defendants gave employees large bonuses for recruiting subjects, and hired people without training to conduct medical research.

In 1997, another researcher was charged with falsifying study results and enrolling ineligible subjects by doctoring patient records.

These are just two of the cases

filed in the past decade that involve fraud and abuse violations in human subjects research. If history is any indication, there will likely be more. **Jim Sheehan, Esq.**, assistant U.S. Attorney in Philadelphia, who has personally handled or directly supervised more than 500 health care fraud cases, said some areas that will soon be under additional scrutiny. These areas include consent issues involving the use of blood and tissue samples, marketing posing as research, and securities fraud among those with access to research information.

Some of the past fraud and abuse cases involve researchers > p. 2

Take care to obtain consent

Just because your human subjects have signed the informed consent form doesn't mean the informed consent process is complete.

In many cases subjects will need to go through the consent process more than one time over the course of a clinical trial.

There are a number of reasons to reconsent a subject according to **Robert Nicholas**, a partner with the law firm of McDermott Will and Emery in Washington, DC.

The key question to keep in mind is: Would a new piece of information or circumstance cause a subject to reconsider his or her participation in a particular study?

"Some of these are very fine judgments. My rule of thumb is if you have enough questions about a situation you should probably [reconsent a subject]," says Nicholas.

The following are the most common reasons for a subject to reconsent subjects:

An initial consent was not conducted or

> p. 7

Avoid fraud

< p. 1

who intentionally violated the law for personal—often monetary—gain. In other instances, organizations have gotten into trouble inadvertently, because they didn't understand the regulations or were careless when it came to compliance.

"These are not issues that affect just fringe players in the industry," said Sheehan. "They are issues that can bring down or at least affect the careers and practice of major, major players, who, in some cases, believe they are doing the right thing," he said. One recent clinical trials case, he said, involved a former president of the American Heart Association, who was temporarily barred from conducting research because of records falsifications that occurred on his watch.

Sheehan and **Carin Sigel**, a partner with the law firm of Gardner, Carton and Douglas LLP in Washington, DC, recently discussed issues of fraud and abuse in clinical trials at an audioconference sponsored by HCPro, Inc. in Marblehead, MA, called "Clinical trials compliance: Eliminate fraud and abuse in your human subject research." They examined recent cases and talked about the most common violations. More importantly, Sheehan and Sigel offered suggestions on how your organization can avoid these problems, which can lead to fines, jail time, and debarment.

Recruitment

An area in which problems most commonly occur is subject recruitment, according to Sheehan. "Every clinical trial entity that I've worked with has difficulty finding a sufficient number of subjects for research," he says.

In a business where recruitment often translates directly into big money, there can be a huge incentive to cheat when it comes to bringing subjects into trials. A number of researchers have been accused by the government for falsifying subject records to help them qualify for trials. In one case, a principal investigator kept qualifying x-rays and urine samples on file to use for a patient who didn't meet

the eligibility criteria.

The practice of offering recruitment bonuses to principal investigators (PI) or staff exacerbates the problem, according to Sheehan. "We've seen cases where clinical coordinators were given \$500 a head to enroll subjects in a trial," he says. This creates a huge incentive to cut corners.

In some cases researchers have gone as far as to create ghost subjects—non-existent participants enrolled by researchers. Records are then falsified to simulate their participation.

Informed consent

Researchers also need to ensure informed consent. Some researchers have forged or falsified consent forms, says Sheehan. Others might be tempted to give subjects incomplete or even false information to encourage participation. In some cases, researchers have forced or coerced subjects to participate in a trial by threatening them with penalties, perhaps suggesting that treatment will be withheld if they do not participate, says Sheehan. In one case, drug-addicted pregnant women were told their children would be taken away once they were born if they did not participate in a trial.

According to Sheehan, researchers must always be certain to tell the subjects the following information:

- ✓ The trial is blinded, which means that they will not be told whether they are receiving the placebo or the actual drug
- ✓ They may be harmed by participating in the trial because of the drug or device being tested
- ✓ They may be harmed because they are not seeking an alternative treatment
- ✓ They may withdraw from the trial at any time

Researchers should also be aware of issues that may arise when dealing with blood or tissue samples. A number of recent court cases have centered on subjects' rights regarding the use of tissue for commercial or experimental purposes. Your organization should have a policy in place with regard to samples

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taken from human subjects and the way to properly inform them of how the samples will be used.

Conflicts of interest

A researcher’s substantial interest in the outcome of a trial can also raise legal concerns, says Sheehan. In some cases, investigators are required to certify when there are conflicts of interest and how they will manage, eliminate, or reduce them. These are essentially promises or assertions, and you can’t ignore them, says Sigel. Doing so could result in a violation of the federal False Claims Act (see related sidebar on p. 4).

Other issues may arise with regard to such conflicts as well. “What we are finding more and more is research cases involving securities fraud, where researchers sell stock in anticipation of bad research results,” says Sheehan. “It is important that research institutions ensure that people who have access to information about commercial applications of research do not dispose of security interests or acquire them in anticipation of research results,” said Sheehan.

A third area of rising concern is the practice by pharmaceutical companies of conducting marketing research and billing it as scientific research. There is a potential for kickback violations in this area, says Sheehan.

Approval process violations

Investigators also get into trouble with procedural issues—many times, these are related to interactions with the IRB. Researchers can run afoul of the law if they fail to communicate effectively with the IRB or to carry out its mandates. To prevent problems, it’s critical to ensure that your IRB has all the information necessary to approve the trial, said Sheehan. Investigators must be certain that the trial complies with any and all conditions the IRB sets as contingencies upon approval. The IRB

must also be kept abreast of any changes as the trial proceeds. “Research done without IRB approval is illegal research, and violates a series of state and federal laws,” said Sheehan.

In addition, be certain to meet grant specifications. Legal issues can arise when a researcher makes false statements in a grant application, said Sheehan. For example, a researcher who had been approved for grant funding in one trial was never physically present during the years that the trial was conducted.

Therefore, be certain to follow the grant provisions and conditions, said Sigel. It’s also critical to abide by the following tips:

- ✓ Don’t allow costs that are barred, such as advertising or entertainment costs. “Sometimes folks think we got this money and we can use it for whatever we want,” she said. This is not the case.
- ✓ Account for dollars spent in order to ensure that the money is being spent appropriately.

If you fail to follow these provisions you could find yourself in violation of the federal False Claims Act, Sigel said.

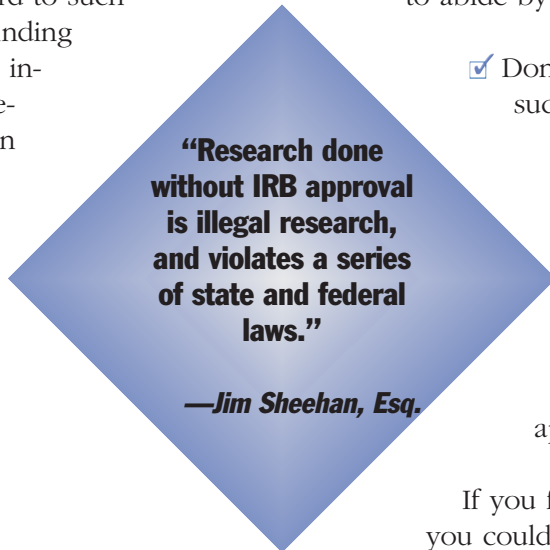
You will also need to ensure that you meet reporting requirements for adverse events that occur during the course of a trial.

Other issues

The following procedural issues may also crop up as your trial progresses:

- ✎ Failure to blind the placebo.
- ✎ Falsification of research results. For example, in one gene therapy case, the results reported in a journal did not have any basis in the bench materials in the laboratory, said Sheehan.
- ✎ Ghostwriting of research papers. “It’s not scientifically appropriate for a person who didn’t

> p. 4



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Avoid fraud

< p. 3

conduct the work to put his or her name on it as the author . . . in my own view, ghostwriting should not be allowed,” said Sheehan.

Researchers, said Sheehan, might want to look at the Web site of Alan Milstein, a defense attorney who has filed a number of cases involving researchers and clinical trials. “You may disagree with a lot of things in Milstein’s cases, but this is where the law is going at the moment,” says Sheehan.

He also suggested that researchers remain abreast of the compliance guidelines that are being developed by the Office of Inspector General. (For more information on these guidelines see the November **CTC**.)

The comments period related to these guidelines closed on November 5, and the guidance will likely be released in the next six months to a year, according to Sheehan. ■

Fraud and abuse laws: The basics

When it comes to issues of fraud and abuse in clinical trials, three federal laws generally come into play, according to **Carin Sigel**, a partner with the law firm of Gardner Carton & Douglas in Washington, DC. They are as follows:

- #1. Federal False Claims Act
- #2. Anti-Kickback statute
- #3. Stark law

Federal False Claims Act

Most fraud and abuse violations in research fall under this area, said Sigel. The federal False Claims Act prohibits the “knowing submission of fraudulent false claims,” she explained. There must be knowledge of or reckless disregard on the part of an individual or institution for this provision to apply. For example, an institution would be in violation of the False Claims Act if it deliberately disregarded a grant restriction, Sigel said.

Violations can result in the following penalties:

- ✓ Damages up to three times the amount of the claim
- ✓ Penalties up to \$11,000 per claim, in addition

to triple damages

- ✓ Exclusion from the Medicare/Medicaid program
- ✓ Employers can be held liable for the actions of employees

Researchers are most vulnerable under the False Claims Act when they seek reimbursement for research-related costs and when dealing with grant awards.

Investigators must make certifications throughout the awards process. Be aware that grant applications can be sometimes be “murky documents,” according to Sigel. If you do not verify the truth and accuracy of the claims, you risk False Claims Act violations. Researchers can also run into problems if they fail to meet all grant provisions and conditions.

In addition to the grant process, a number of certifications throughout clinical research trials are also vulnerable to false claims. This applies more to the federal-wide assurance programs where grant recipients must agree to comply with HHS regulations, said Sigel.

Medicare reimbursement

Trials that receive Medicare reimbursement are also subject to the False Claims Act. In 2000, the government issued a national coverage decision, declaring that the government would reimburse certain routine costs related to clinical trials. However, if you are billing for trial-related expenses, it's critical to avoid the following potential pitfalls:

- **Billing Medicare for something that is paid for by the sponsor.** Be careful not to double bill. The sponsor often pays a fee per subject. If you're going to bill Medicare, keep solid documentation that details where, when, and why you are billing whom to ensure that there is no duplication.

- **Billing for experimental services.** Medicare does not cover costs related to experimental procedures. It only covers costs that are considered treatment. For example, if a subject in a drug trial is given one CAT scan to see whether the growth of a tumor has been halted, Medicare will likely cover that cost because it might also be a typical part of treatment for that condition. However, if a subject underwent multiple scans that wouldn't normally be given to a patient with the same condition, they would be considered experimental and the site would not be permitted to bill for them.

Internal audits

When examining your systems to ensure that your organization does not violate the False Claims Act, the best place to start is to look for the flow of money, Sigel said.

Look at the following financial relationships for

signs of problems:

- Sponsor and the principal investigator (PI)
- Site and the PI
- Sponsor and the site

Anti-Kickback statute

Under the Anti-Kickback statute, it is a felony to receive knowingly and willingly—directly or indirectly—any remuneration for

- ☞ referring an individual to an entity
- ☞ purchasing, leasing, or ordering items/services
- ☞ items/services paid for in whole or in part by Medicare, Medicaid, TriCare or other federal health care program

Penalties may include \$25,000 for each offense, five years imprisonment, civil monetary penalties, and exclusion from federal health care programs.

When looking for potential violations, take steps to ensure that research grants are bonafide. There have been cases in which the proposed research was of little value, and the grant to the physician was actually a disguised kickback.

Sigel says the following questions and tips can help prevent your institution from committing an Anti-Kickback violation:

- ☑ Look at your research budget. Are services being provided at fair market value? If so, has the value of the services been determined in a way that can be documented?
- ☑ Examine all agreements, and look for anything that might be hidden.

> p. 6



The basics

> p. 6

- Ensure that studies are appropriately staffed and that all staff members are providing services for the clinical research. Pay attention to whether there are too many high referrers included as investigators.
- Develop policies that call for the return of or place limitations on excess funds. Residual funds were not a big concern in the past—when money was left over, it was often overlooked or would go into a hospital fund—but today these excess funds result in a conflict of interest.
- Be wary of fancy, over-the-top vacations or conferences. Ensure that meeting sites are reasonable and practical. Meetings must be substantive and of value to the research.

One means of protecting your organization against Anti-Kickback violations is to comply with safe harbor provisions whenever possible. Anti-kickback regulations have a number of such safe harbors, and if you meet their criteria, you will not be prosecuted under the law.

“If you don’t meet the safe harbor criteria it doesn’t mean the arrangement is illegal; it just means you are not protected,” said Sigel.

Stark law

The Stark law only applies when a physician is involved in a case—in a clinical trial, this would be the PI (or his or her family member). This provider is prohibited from referring Medicare, Medicaid, or TriCare patients to an entity that provides designated health services if that provider has a financial relationship with the entity. This law typically does not apply to private industry sponsors.

Penalties for violating the Stark law include the following:

- \$15,000 per service
- potential exclusion from federal health programs

Most health care services have a relationship to the physician and designated health care services provider that would be subject to Stark law, and cannot be the referrer of a Medicare or Medicaid patient to the entity for the provision of the services unless an exception is met. Some of these exceptions are similar to those within the Anti-Kickback statute. If Stark law is triggered you must meet an exception or you will be in violation of the law. It’s a civil law, not a criminal law, but it carries significant monetary penalties. ■

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Obtain consent

< p. 1

was insufficient.

- ✓ A new risk to the subjects of the trial has been discovered. This might include the discovery of an adverse event, such as high blood pressure. This adverse event represents an additional risk that was not considered by the subject when he or she initially consented to the trial. Therefore, subjects should be reconsented so they are aware that the risks of the trial have changed.
- ✓ A new procedure is added.
- ✓ A minor reaches the age of consent, or a person who was unable to offer consent obtains the legal capacity to make his or her own decision.
- ✓ The protocol is amended and the conditions of the trial have changed. For example, the length of the trial is being extended by a year.

Depending on the reason for doing so, reconsenting a subject can be part of a scheduled visit or of a special visit to ensure he or she has the necessary information as soon as possible.

Consider the following points when deciding how soon the reconsenting process should take place:

1. Is this truly a new risk or is it a nuance of an already known risk?
2. Could this information cause a subject to reconsider his or her participation in the trial?

Some trials should have the opportunity to re-consent subjects built into the process. Subjects should know that they have the right to withdraw at any time; however, if there is some concern or an indi-

cation that this may not be sufficient, an IRB can require the researcher to renew informed consent at a midpoint or other specified time in the trial. This might occur if a trial is long or if the hardships it might entail are not evident early in the process.

IRBs should be involved

IRBs should play a key role in ensuring that subjects are properly informed at the outset and throughout the trial, says Nicholas. IRBs should consider the following:

1. When a protocol amendment is filed or a new adverse event risk is identified, the board should know that the trial may need a new informed consent form.
2. If the board is asked to approve revisions to the consent form, it should determine whether the changes are sufficient to require existing study subjects to undergo a renewed consent process.
3. IRBs should watch for appropriate times to give subjects a chance to reconsider their participation, such as if an investigator leaves or is terminated from a trial.

The HIPAA privacy regulation, effective since April, should also be a consideration in the reconsenting process.

Trials that began prior to the implementation date are exempt from the mandates; however, if the circumstances of a trial change you might need to get a HIPAA authorization from your subjects or a waiver from your IRB.

For example, if a researcher decides he or she wants to use subject information for a secondary purpose, it may require a HIPAA authorization, unless the information is de-identified. ■

“IRBs should play a key role in ensuring that subjects are properly informed at the outset and throughout the trial.”

—Robert Nicholas



Chinese fertility trial sets off ethical debate

A Chinese fertility experiment has raised an important question in the scientific community: Should American researchers who conduct trials overseas be subject to the same oversight requirements as those who conduct trials on U.S. soil?

An American scientist, Jamie Grifo, developed the idea for the Chinese fertility experiment, which replaces the nucleus of a donor egg with genetic material from another set of parents, according to *The Baltimore Sun*. The researcher opted against conducting the research in the United States because he would need approval from the Food and Drug Administration (FDA), which he felt he was unlikely to receive. Instead, he passed the idea to Chinese researchers. They conducted the experiment, which impregnated a Chinese woman with triplets, the *Sun* reported.

The triplets did not survive, due to pregnancy complications that were reportedly unrelated to the procedure. Some ethicists quoted by the *Sun* called for regulations that would prevent researchers from moving questionable research projects overseas.

Others, including **Adil Shamoo, PhD**, an ethics expert and professor at the University of Maryland in Baltimore, say attempting to prevent such practices would result in “draconian rules” that would be difficult, if not impossible, to enforce.

“I see the issue from both sides, but we really have no right to regulate other countries,” he says. It would be very difficult to prevent an American scientist from collaborating with colleagues overseas. For example, how can you regulate information shared at an international conference? “The issues of enforcement would be atrocious,” says Shamoo, who was recently appointed to the armed forces epidemiological board, a position that requires White House approval.

By the same token, Shamoo says he believes scientists should be guided by their own moral compass, and not attempt to circumvent U.S. laws. Individual research institutions can set policies regarding the sharing of information overseas. However, Shamoo says it may take a United Nations action or international treaty to prevent such practices. Handling this issue on a case-by-case basis would be ineffective. ■

Ophthalmologist fined \$1.1 million for study violations

A Louisiana ophthalmologist and the eye care center he owns have been fined \$1.1 million by the Food and Drug Administration (FDA) for a series of clinical study violations, according to a press release issued by the FDA.

Leon C. LaHaye, MD, allegedly committed the violations while testing a laser system designed to treat nearsightedness. Allegations against LaHaye and the center include the following:

- ✓ Using an unapproved laser before the study began
- ✓ Treating more subjects than permitted under

the study plan

- ✓ Treating nearsightedness beyond the permitted range and treating astigmatism in patients—a procedure that was not permitted
- ✓ Failing to submit complete and accurate reports to the FDA

LaHaye had also reported to the FDA that he was using an approved laser to treat patients, but he was actually using an experimental model. The settlement still needs to be approved by an administrative law judge. ■

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OHRP: Taking oral histories doesn't need IRB approval

This fall, the OHRP sent a letter to the Pennsylvania Historical and Museum Commission in Harrisburg, PA, that caused a stir among some IRB members and researchers. The letter stated that “oral history interviewing activities” are not considered research, and therefore do not need to go through an IRB review.

The oral histories in question are typically gathered by historians or social scientists and involve interviewing politicians, military figures, or individuals involved in historical events to gain information about an individual or occurrence. The information gathered might be analyzed or recorded, says **Adil Shamoo, PhD**, an ethics expert and professor at the University of Maryland, Baltimore.

The OHRP letter, however, represents a change from the government's position in the past, says Shamoo. Previously the government's position has been that oral histories must be approved by an IRB because they carry the risk of emotional damage to the subjects. The risks often lie in recalling traumatic experiences, for such subjects as victims of September 11 attacks or war veterans, he says.

The OHRP has determined that oral history interviewing activities “are not designed to contribute to

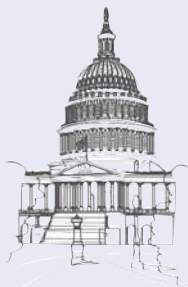
generalizable knowledge and therefore do not involve research as defined by HHS regulations at 45 *CFR* 46.102(d) and do not need to be reviewed by an [IRB].”

Shamoo says IRBs should not necessarily stop reviewing oral history cases just because the OHRP has deemed it unnecessary, although he suspects many IRBs will. He believes these cases might be best decided on a case-by-case basis. “I would not have made such a blanket ruling, but I understand the logic behind it,” says Shamoo.

Institutions may continue IRB reviews in situations where interviews could cause damage to the person you are interviewing—for example a person with post traumatic stress syndrome, Shamoo says.

“I would err on the side of protection,” he adds.

However, in cases where the risk of harm is not as great, IRB time may be better spent looking at cases that pose more significant risks. There is still much ground to cover in ensuring the safety of subjects involved in high-risk experiments, Shamoo says, “before we go and lengthen the arm to reach oral histories.” ■



Government news

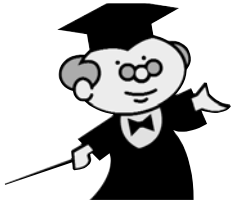
OHRP restructures its administration

The OHRP has made changes to some of its administrative departments, a move officials say will not affect OHRP's “mission, emphasis, or activities,” according to a press release on the OHRP Web site.

Under the reorganization, the Division of Assurances

and Quality Improvement has been broken into two other divisions. The newly formed Division of Policy and Assurances will now handle assurances, and the Division of Education and Development will handle quality improvement. For more information on the change, go to ohrp.osops.dhhs.gov/ and click on “news.” ■

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Ask the expert: Preventing fraud and abuse issues in research

*Editor's note: This month's experts are **Jim Sheehan, Esq.**, assistant U.S. Attorney in Philadelphia, who has personally handled or directly supervised more than 500 health care fraud cases, and **Carin Sigel**, a partner with the law firm of Gardner, Carton and Douglas LLP in Washington, DC.*

These questions were adapted from the audioconference Clinical trials compliance: Eliminate fraud and abuse in your human subject research. To purchase a copy of the tape contact our Customer Service Department at 800/650-6787.

Q #1: Are there any potential pitfalls in contracts that involve a private physician office receiving payments for services that the hospital provided? The hospital will not be reimbursed.

A With very strict exceptions, Medicare does not allow you to bill for a service provided by somebody else. If a hospital provides the service and the physician bills for it, there is an issue of benefit to the physician. Why is the payment set up that way? Who is giving the doctor money for services he or she didn't perform? Billing for services you didn't provide raises fraud questions and potential kickback questions. Whenever we in the government see money given for nothing, it looks suspicious.

Q #2: We have a principle investigator (PI) that can't afford to pay the cost of tests involved with a research study. Does it represent a kickback or inducement if our institution offers to pay for the tests or x-rays in question?

A The benefits you're describing seem pretty third-level. Is the payment for the tests something of value? I don't know the answer to that. Cash in my pocket is something of value. Payment of lab fees so I can conduct the study doesn't seem like an inducement. The answer to this question depends on the circumstances, but the situation

you've described to me doesn't seem like it would be a problem.

Q #3: Currently, deemed trials are the only ones that can seek reimbursement from Medicare. We've been waiting for a while now for the government to allow researchers to self-certify trials, which would allow trials that aren't deemed to receive reimbursement. Is there any chance that self-certification standards will be developed in the future?

A Predicting reimbursement changes from CMS is a hazardous activity. It appears that for the foreseeable future, deemed trials will be the only ones eligible for reimbursement.

Q #4: There was a recent court case in which IRB members were sued individually. Is this something IRB members should be concerned about?

A These IRB members were sued under the theory of negligence. These IRB members were charged with not properly and appropriately reviewing the protocols and the research. IRB members have a duty to the subjects of the study and can be sued for breach of that duty, at least under the theory developed by attorney Alan Milstein, who filed the suit in question.

This suit and others like it have resulted in significant settlements, and although no judge has ruled on them, it's safe to assume that IRB members have some legal exposure. The institution should have insurance to cover the work of the IRB to protect it if it is sued. It's tough enough to ask someone to sit on an IRB without offering that type of protection.

Q #5: Where else besides in advertising is therapeutic misconception a problem?

A This is a very good question. The most

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common situation in which I see it is when a practicing physician allows his or her patient base to be combed for potential research subjects. Problems can arise depending on how those patients are contacted and by whom.

Overall, there is a core problem that I've seen in research. That is, even if you've done everything required by the IRB to ensure that subjects are properly informed, you will still have 25%–50% of patients who believe that the physician wants them to take part in the study for the patient's benefit. For this reason, it's critical to take the following steps:

- Develop good IRB guidelines regarding consent
- Ensure that your consent form is adequate
- Videotape the consent process

The question will be whether a good faith effort was made. There are some cases in which physicians and subjects believe the trial to be the final hope in treatment. The government is probably not going focus cases involving terminal cancer patients, for example. It is going to focus on fraud cases. In those cases, the recruiter may have been motivated by money.

These cases will often involve a recruiter who plays on the weaknesses of patients. Situations where both the physician and the patient want to believe that this is going to benefit them may not be good science, but it's not going to be the subject of fraud

prosecution.

Q #7: The government has said it doesn't want to see research coming from the marketing division of a pharmaceutical company. However, there are a limited number of research projects that aren't driven by pharmaceutical marketing departments. Do you feel that this type of research is okay if it is well done and the science behind it is solid?

A You are correct that much research is driven by a drug company's desire to say there is a clinical difference between their drug and a competitor's or the placebo. However, there are issues that can make this type of research problematic. The main concern is whether the scientist has the independence he or she needs to conduct a valid trial. There are cases in which the marketing department will choose a start point or end point in the trial.

For example, it might know that a competitor's drug takes nine months to work, and set the end point of the trial comparing the two drugs at six months. In other cases, the pharmaceutical company might retain right of first refusal over trial results or veto power over the reporting of those results.

These are the types of issues that raise concerns, not just who is paying for the trial. The researcher needs to be sufficiently independent to say, "this is what I did, this is the protocol, and this is the result I got." ■

FDA issues draft guidance on electronic submissions

In October, the Food and Drug Administration (FDA) released the first in a series of guidance documents related to electronic submissions, *Providing Regulatory Submissions in Electronic Format—General Considerations*.

The draft guidance addresses issues that affect

electronic regulatory submissions. It represents the revised version of the January 1999 guidance of the same name.

Go to www.fda.gov/OHRMS/DOCKETS/98fr/2003D-0465-gdl0001.pdf to read a copy of the guidance. ■

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Accreditation news: AAHRPP appoints new officers

The Association for the Accreditation of Human Research Protection Programs, Inc. (AAHRPP) has announced a number of new officers, who will serve a two-year term. The new president of the board is **Barbara Bierer, MD**, senior vice president for research at Brigham and Women's Hospital in Boston.

"I am a true believer in the importance of accreditation as a means for organizations to demonstrate their commitment to human research protections, and have proudly served on the AAHRPP board since its inception," she said in a written release. "For hospitals and academic institutions engaged in clinical research, accreditation has a particularly high value."

She replaces **David Skorton, MD**, president of the University of Iowa.

The other new officers are as follows:

- Vice president—**Mark Brenner, PhD**, associate vice president for research, Indiana University and vice chancellor for research and graduate education Indiana University-Perdue University Indianapolis Campus.
- Secretary (second term)—**Steven R. Smith, JD**, president and dean California Western School of Law
- Treasurer—**Richard Gelula, MSW**, executive director, National Sleep Foundation

"The board that represents the institutional diversity of human research did an excellent job in helping guide AAHRPP through its first two years, and we are very pleased that the new officers have agreed to serve," said Marjorie Speers, PhD, executive director of AAHRPP. ■

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For news and story ideas:

Contact Managing Editor Kelly Bilodeau

- Phone: 781/639-1872, ext. 3298
- Mail: 200 Hoods Lane, Marblehead, MA 01945
- E-mail: kbilodeau@hcpro.com
- Fax: 781/639-2982

Executive Editor, Lauren McLeod
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