Take steps to develop policies regarding residual balances

A residual balance at the end of a clinical trial can signal a problem. Residual funds are the dollars that remain after all costs associated with the study have been paid—including indirect costs.

Leftover money can mean someone that the organization should have paid didn’t get the money, or that it billed services to someone it shouldn’t have—such as a third-party payer such as Medicare. In some cases, a large residual can indicate that the investigator received a financial incentive to complete the study—which raises conflict of interest issues for your institution, according to Matthew Purner, senior associate in the education advisory services department for PricewaterhouseCoopers, LLP, in Los Angeles.

That’s not to say residual balances are never legitimate, but in the majority of cases trials should break even, he says.

“I think one of the reasons that people are struggling with [residual balances] is because their institution doesn’t have a clear-cut policy,” says Purner.

Some institutions have

Case study: Taking part in the OHRP Quality Improvement Program

Generally, when government auditors show up at your facility, it’s no cause for celebration. So why would an organization go out of its way to invite them in?

Children’s Hospital in Boston recently did just that when it decided to take part in the Office for Human Research Protections’ (OHRP) Quality Improvement (QI) Program.

The program, which was launched in January 2002, can be an effective means of assessing and improving your research program, says Susan Kornetsky, MPH, CIP, director of clinical research compliance at Children’s. “We were one of the first [to go through the program],” says Kornetsky. Since the summer of 2001, when the pilot program began, 33 organizations, including six academic institutions in South Africa, have participated in the program.

The process, Kornetsky says, was valuable—and one she highly recommends to other organizations.

“It’s a good idea to have the office responsible for interpreting the regs come in and assist you,”
Residual balances

hesitated to develop policies on this issue because research is seen as a means of making money. With no limits on the amount of residuals permitted, some investigators may wind up with a good chunk of change at the end of a study, Purner says.

Although the government doesn’t have any specific regulations addressing residual balances, institutions should keep in mind that residual balances can often raise conflict of interest issues, which are addressed in federal regulations, he says.

Developing a policy

To avoid potential problems, your institution should develop a clear policy regarding residual balances that should spell out:

- how much of a residual is too much
- where the extra money can go

For example, the residual balance could be used as “seed money,” for department funds, or go into an investigator’s pocket.

Generally, a study should have no more than a $5,000–$10,000 residual balance at the end of a trial.

“If an investigator has a really high residual balance it should really raise a red flag,” Purner says.

If a trial does have a large balance, it brings up the following questions:

- Were services not rendered?
- Were costs billed to the research account?
- Was a third-party payer such as Medicare erroneously billed?

For example, if a study is granted $1,500 per study subject, and the study is slated to enroll 10 subjects, the total cost of the study should be $15,000, says Purner. If an investigator has $7,500 left over at the end of a study, you need to ask why.

It could be that the site enrolled fewer than 10 subjects. “Then you need to ask why were they paid for all of them,” says Purner.

There are legitimate circumstances, however, that would lead to a residual balance, says Purner. For example, a sponsor might decide to pay multiple sites a standard $2,000 per subject. The cost per subject could actually be lower, which would leave you with a residual balance.

Where can the money go?

If a residual balance is warranted, the organization should stipulate in a policy how that money can be used.

Many organizations permit the money to be used as “seed money” to help new projects get started, or they pool it in a departmental fund. Purner says some organizations may opt to allow investigators to keep the money as personal income—but doing so may raise conflict of interest issues.

Allowing investigators to pocket the extra money could be seen as a financial inducement, could impair the researcher’s independence, and could even affect the integrity of the study itself. A potential conflict could also put patients at risk.

However, Purner says, while none of the organizations he works with permits investigators to take the residuals as personal income, some might decide it is permissible in certain circumstances. “I’m not saying that it couldn’t correctly be done,” he says. But organizations that do permit it should be aware they could be getting into dangerous territory.

TIP: Keep in mind that if you do permit investigators to keep the residual funds as personal income, it needs to be taxed according to federal
Case study

she says.

The program consists of a self-assessment, followed by a site visit. It was designed as a means of helping organizations improve their programs, and consequently, research protections for human subjects.

Mindful that many organizations might be wary of inviting government auditors into their facilities, OHRP designed the program so that it was isolated from its compliance division.

“OHRP divided its functions. They have compliance on one side and QI on the other,” says Kornetsky. This design was to ensure that the two functions remained separate.

“Our approach is collegial, collaborative and focused on prevention of harm to research subjects. If we identify procedural non-compliance, we work with the institution to develop appropriate corrective actions,” says Yvonne Higgins, acting director of OHRP’s division of assurances and quality improvement. “Many of these changes can be implemented during the visit. Some require follow up by the QA [quality assurance] team.

“If the QA team identified serious systemic non-compliance or serious problems that resulted in harm to research subjects, we would notify the institutional official and Dr. Schwetz, OHRP acting director. OHRP would work intensively with the institution to remedy the problem in a timely fashion and we would require the institution to file a formal corrective action plan with our office,” Higgins says.

Kornetsky says “[OHRP has] kept its word by keeping things confidential.” The creators of the program were also careful to set up a mechanism to prevent the information in the reviews from being subject to the Freedom of Information Act. “That was very important, otherwise no one would have agreed to [go through a visit],” Kornetsky says.

In addition to getting feedback from government regulators about the status of your program, the QI visit bring an added benefit—participating in one can keep OHRP from showing up at your door for a not-for-cause compliance audit. “If an institution participated in a QA consultation within the past two years, it is very unlikely that it would be selected for a not-for-cause compliance audit,” says Higgins. However, keep in mind that it doesn’t exempt you from a for-cause compliance visit if you have a problem, says Kornetsky.

“It costs nothing, and I don’t think there is any way you can go wrong,” she says. “This is one way that you can deal with federal regulators and not be threatened or concerned.”

The process

“The first component [of the QI program] is a self-assessment,” says Kornetsky. The self-assessment consists of a form that you fill out. Organizations are asked to answer questions about how they run their programs. “It gives you the opportunity to step back and look at the whole program,” says Kornetsky, giving you back some of the perspective you tend to lose being involved with the program every day.

“It probably took me three or four hours [to complete],” says Kornetsky. But the time you would need to spend on the self-assessment depends on the size of your program, she adds.

Some of the questions on the form involve regulatory issues—things you should be doing according to the regulations. Other questions involve best practices, things that go above and beyond the regulations. “An experienced person would pick up on the
Case study

OHRP gave Children’s a suggested schedule (see box below) and a list of people the auditors wanted to meet. “We followed their schedule, plus added a few people we thought were important,” says Kornetsky.

The visit lasted for a day and a half. First the OHRP team spent time with the IRB members and office staff. “It wasn’t an intensive record review, unlike a compliance visit,” she says. It focused more on interviewing people within the organization. “The purpose is for people to openly share their impressions,” says Kornetsky. In this setting, people are more likely to honestly share their feelings about the program—information that may be difficult for an institutional official to gather.

When the site visit concluded, the OHRP team had an exit meeting with an organization leader. “We happened to do extremely well,” says Kornetsky. “They were very impressed with our program. They said it’s very obvious we’ve had a strong program for a long time.”

OHRP gave Children’s a suggested schedule (see box below) and a list of people the auditors wanted to meet. “We followed their schedule, plus added a few people we thought were important,” says Kornetsky.

After completing the self-assessment you will have some idea about how your facility is doing, says Kornetsky. However, the tool is incomplete without feedback from OHRP team members. “I had specifically requested that someone come to on site for an evaluation,” she says. “I thought it was very, very important.”

The site visit
Generally, when the OHRP comes for a compliance-related visit, auditors only interact with IRB staff and the people in the research office. But the visit involved others who weren’t necessarily used to working with the OHRP—the investigators, vice president for research, general counsel, and the research subjects’ advocate.

differences,” she says.

Kornetsky says she likes the fact that the best practice questions are on the self-assessment, because it gives sites something to strive for in the future. “I think that’s what quality improvement is,” she says.

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Case study

- Interview with institutional officials, 20 minutes
- Interview with institutional officials, IRB chair and director, 20 minutes
- IRB, 20 minutes
- Tour of IRB office, operations and files, 20 minutes
- Record review (OHRP staff only), approximately two hours
- Review of operating procedures, IRB minutes/self-assessment tool with IRB director and appropriate staff, one hour

Sample schedule for the OHRP quality improvement consultation visit

Go to http://ohrp.osophs.dhhs.gov to see the following schedule on the OHRP Web site.

Day one:
Begin around 1 p.m.

- Interview with institutional officials, 20 minutes
- Interview with institutional officials, IRB chair and director, 20 minutes
- IRB, 20 minutes
- Tour of IRB office, operations and files, 20 minutes
- Record review (OHRP staff only), approximately two hours
- Review of operating procedures, IRB minutes/self-assessment tool with IRB director and appropriate staff, one hour

Day two:
Begin around 9 a.m.

- Interview with IRB chair, 40 minutes
- Interview with director of IRB office and IRB coordinator, one hour
- Break, 10–15 minutes
- Interview with IRB members, 40 minutes
- Lunch, one hour
- Interview with group of investigators, 40 minutes
- Interview second group of investigators, 40 minutes
- Break, 1–15 minutes
- Question and answer period, 60–90 minutes
- Break to prepare quality improvement team for exit interview, 15 minutes
- Exit interview with institutional officials, IRB chairperson and director of IRB, 30 minutes
But there were also areas for improvement. The audit team suggested minor changes, including tweaking the language used in IRB meeting minutes so that minutes are clearer.

The team from OHRP also noted that there was some frustration on the part of IRB members because they got little recognition for serving on the board. While they enjoyed their position, they felt that considering the amount of work they did, they should have gotten more recognition.

The OHRP team members shared these impressions with hospital officials, who have since taken steps to better recognize IRB members for their service. Sometimes a comment such as this gets more notice when it comes from an outside official—particularly from the OHRP, says Kornetsky.

Another benefit of the visit is that OHRP team will also share best practices with organizations to help them improve their practices, based on policies or procedures that other organizations are using successfully.

In addition to verbal feedback, the ORHP team also gave the hospital a written report. It was about a page and a half long, Kornetsky says. But it might have been longer if the facility had more areas flagged by the OHRP.

The QI program would be a boon for anyone considering going through one of the two voluntary accreditation programs now available for research programs—the Association for the Accreditation of Human Research Protection Programs (AAHRPP) and the Partnership for Human Research Protection, Inc. “This can be looked at as a first step in getting ready for accreditation,” says Kornetsky.

Kornetsky, who is on the board for the AAHRPP says that this process does not duplicate the accreditation process—rather it complements it. The accreditation process is much more intensive, she says.

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**Harvard considers relaxing financial conflict policy**

Two faculty committees at Harvard Medical School, in Cambridge, MA, may recommend easing policies that limit consulting fees and stock ownership in companies that finance research, according to the Associated Press.

The current policy prevents researchers from owning more than $20,000 in stock in companies that finance research they are involved with. It also prohibits researchers from spending more than 20% of their time on non-Harvard research. They are additionally barred from taking more than $10,000 in consulting fees from those companies. Those who support the changes say this would provide rewards to faculty members involved in research, consequently speeding up the process of turning discoveries into useable medicines.

However, others say relaxing the policy could compromise the integrity of research at Harvard and could create conflict of interest issues. Owning a large amount of stock in a company you are conducting research for is no different than insider trading, says Adil Shamoo, PhD, a research scientist and professor at the University of Maryland, Baltimore.

It is unrealistic to think that a person who owns a $500,000 in company stock won’t be influenced by that fact when they are conducting the research, says Shamoo. He does not agree that relaxing the standards will improve the efficiency of research. Shamoo believes that Harvard’s current policy should remain intact, since it is “influential as a role model for the rest of the academic community.”

The faculty committees were expected to recommend for or against a policy change on June 26.
Tracking disclosures to meet the HIPAA requirement

Under the HIPAA privacy regulation, patients and subjects have a right to know who has been given access to their protected health information (PHI). This means that health care organizations have a new obligation to track disclosures so they can give patients the information if they request it.

Not all disclosures must be accounted for. Under the HIPAA regulation, information that is used for treatment, payment, or health care operations is exempt. There are a number of categories of information, however, that must be shared—and among them are research disclosures without written patient authorization. (See box below.)

This means researchers will have new responsibilities when it comes to tracking disclosures. It also may hinder their ability to get information from organizations to perform research.

“There is a concern that some organizations won’t allow researchers access to data because they don’t have systems in place to account for the data,” says Lawrence “Doc” Muhlbaier, PhD, a faculty statistician and IRB member at Duke University in Durham, NC. Hopefully, however, this will be a short-term issue for researchers if it arises at all.

Covered entity bears the burden

When it comes to accounting for disclosures, it is actually the covered entity—the organization—that bears the responsibility. But while the covered entity has to do the accounting, the researcher is still in some sense responsible.

“If they weren’t doing the research, there would be no disclosure to account for,” says Muhlbaier.

If the researcher is part of the work force of the covered entity, then the disclosure occurs when the information is sent outside, perhaps to a sponsor. In this case, because the researcher is part of the covered entity, he or she will likely have the responsibility

What type of information must be disclosed?

The HIPAA privacy regulation requires that certain types of information be disclosed upon the patient/subject’s request. They are as follows:

1. Public health authorities disclosures, such as births and deaths, child and elder abuse, and communicable diseases
2. Food and Drug Administration adverse events, product defects, biological product deviations, or post-marketing surveillance
3. Information disclosed for purposes of medical surveillance, work-related injury or illness, Occupational Safety and Health Administration, or similar state law
4. Health oversight related to government benefit programs, compliance, civil rights laws, trauma registry, tumor registry, and vital statistics
5. Court orders or subpoena
6. Law enforcement disclosures required by law, such as court orders, warrants, subpoenas, summonses, or administrative requests
7. Disclosures about the deceased to medical examiners, funeral directors, or for organ donation purposes
8. Research disclosures without written authorization
9. Military and veterans activities and protective services
10. Workers compensation

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for recording those disclosures, says Muhlbaier.

Different organizations will have different systems for tracking these disclosures. Smaller covered entities, single sites, or clinical practices could track them by keeping a log in the front of the patient’s chart. At Duke University, they are using a centralized system, which allows individuals to input disclosures as they occur. The researchers are responsible for documenting any releases of information—for example, when documents are sent to a sponsor.

“I think whether you use a centralized or decentralized system will be a function of the size and complexity of your facility,” says Muhlbaier.

Outside researchers
The responsibility for accounting for disclosures, however, shifts when the researcher is not considered a member of the work force at a covered entity. For example, this might be a physician in private practice seeking access to hospital documents to recruit patients to a study.

“In this case, the researcher receiving PHI is itself a disclosure,” says Muhlbaier. “That would mean that it would be the responsibility of the covered entity, and not the researcher, to do the accounting tracking.” People should know whether they are a part of the covered entity or outside it already because of the training required under the HIPAA regulation, he says.

Requests for information
If a subject requests an accounting of disclosure, it must be given to him or her within 30 days. If that deadline cannot be met, an extension may be requested, which would give the organization an additional 30 days to produce the information.

“But you have to have the [disclosure] list done in 60 days,” says Muhlbaier, or you risk violating the regulation.

The medical records department is handing all requests at Duke. For university officials it seemed the most logical place to establish as a point of contact.

What you need to disclose under the HIPAA privacy requirement

- Date of disclosure
- Who received the information
- Recipient’s address (if known)
- A description of what was disclosed
- Why the information was disclosed

“Disclosure accounting is much broader than research. The covered entity will consider research as one of the pieces in the broader requirement,” says Muhlbaier. As for the information to be released, there is no specific guidance in the regulations indicating how detailed the information needs to be.

At Duke, the information is given in fairly broad strokes, with an eye toward making the information easily understandable for the average subject. (See related box above.) To do this, disclosure accounting information is written in language similar to that on informed consent documents.

For instance, the form might say admission laboratory values were provided to an outside party, rather than list the technical name of the laboratory values that were released.

Muhlbaier says it’s a good idea to use informed consent language guidelines as your template. Any language that wouldn’t make it into an informed consent shouldn’t be used in a disclosure statement.

Will patients request information?
Muhlbaier says there is going to be some demand for accounts of disclosures by patients.

“Pretty much everybody who works in a hospital will probably request it. I plan to,” he says. “But I’m going to give it a year or so to ensure they have enough data to account for.”
Medicare reform bill could expand research coverage

Editor’s note: This column was written by Nick Raio, a freelance writer from Northport, NY.

Medicare may finally have to cover routine costs of clinical trials for investigational devices if Congress passes new proposed legislation.

The Medicare Innovation and Responsiveness Act of 2003 (MIRA) will not only make it easier for medical device companies to include senior citizens and the disabled in their clinical trials, but will also speed up access to those products once they are approved by the Food and Drug Administration (FDA).

Currently, Medicare policy is seen by some to be impeding the development of innovative technology—such as heart assist devices—by not providing reimbursement for routine care costs during some clinical trials.

The Centers for Medicare & Medicaid Services (CMS) extended Medicare payments for routine costs associated with certain qualifying clinical trials several years ago, but not all clinical trials were included.

CMS said in 2000 it would implement a presidential executive order to provide reimbursement for the routine costs of care for breakthrough medical technologies, but it has yet to finalize this policy. Many of the overlooked trials are now being addressed by the bill introduced this year by U.S. Representatives Jim Ramstad (R-MN), Anna Eschoo, (D-CA) and Joseph Pitts (R-PA). MIRA will also require CMS to construct a system for timely appeals that will apply to multiple cases in order to eliminate bureaucratic redundancy.

“This bill was introduced in Congress in 2002, but never made it out of committee,” says Linda Bentley, an attorney specializing in clinical trials and regulation of new medical technologies for the law firm of Mintz, Levin, Cohn, Ferris, Glovsky and Popeo in Boston.

“This bill will clear up uncertainty for hospitals regarding the clinical-trial related services that can be billed to Medicare,” Bentley says.

A device that has received a lot of publicity is the AbioCor—a replacement heart manufactured by Danvers, MA–based Abiomed that is undergoing clinical trials.

According to Bentley, Medicare traditionally would not have paid for routine costs associated with the clinical trial for this device.

However, MIRA would address exactly this type of cost—which has been overlooked under previous regulations.

House Bill 941 is expected to establish an “open,
transparent, and rational” public process for incorporating new tests and will provide clear explanations of the basis for determinations on new technology.

The public will have unprecedented access to data considered as part of the determination process. In addition, the bill will establish “principled methodologies” for setting prices for new technologies, and developing “fair and appropriate payment levels” for medical devices and procedures.

MIRA would force CMS to keep its commitment to cover routine costs of clinical trials of breakthrough medical technologies, but the new policy would have little effect on Medicare spending, as breakthrough technology accounts for just 6% of FDA-approved studies.

Medicare patients will, however, see vastly improved access to such devices as artificial heart devices, bio-artificial livers, kidneys, and “bionic eyes” to treat blindness.

“Right now, it can take more than a year until a medical device or drug that is approved by the FDA is made available to Medicare beneficiaries,” she says.

“Although these delays can be due to several causes, the bill would make the coding landscape faster and more responsive to the introduction of new technology.”

Currently, most billing operations are using the ICD-9-CM coding system and many hope that if MIRA is passed it will enable new adoption of the ICD-10-CM code as a standard for the reporting of hospital inpatient services without a recommendation by the National Committee on Vital and Health Statistics.

This will result in quicker decisions on coverage of new products and services by Medicare.

MIRA will require CMS to update codes quarterly and approve and implement new codes within 90-180 days. Medicare typically takes two years or more to update its inpatient reimbursement rates to reflect changes in medical technology.

Congress passed the Benefits Improvement Act of 2000 to reduce these delays by establishing transitional payments for new medical technologies, but CMS’ implementation of the new law was seen by some as insufficient to fulfill the intent of Congress to address these concerns.

Timely decision-making and increased accountability for coverage decisions are expected to ultimately improve patient access and provide incentive for smaller research outfits to pursue development of new medical technologies.

Policies adopted during the Clinton administration began to address concerns associated with clinical trials as to what would be covered by Medicare, but Bentley says MIRA will close the gap in regard to medical devices and new technologies. “It will make it much clearer as to what is considered a routine cost,” she says.

“There have been whole classes of medical devices which are classified as innovative and as a result have not been covered,” she comments.

Bentley continues, “the concern has always been that the elderly have not had access to these new, innovative technologies, hopefully, MIRA will address this issue.”
Society urges changes to improve research oversight

The American Society of Clinical Oncology (ASCO) made several recommendations in a special article published in the June issue of the Journal of Clinical Oncology. The organization said these steps, summarized below, will improve clinical research oversight. It said it plans to work with everyone involved to implement the recommendations.

Centralized trial review
This concept proposes using central IRBs organized through the National Cancer Institute’s system of cooperative groups. The use of “highly trained” central IRB members to review trials would allow local IRBs to focus on the continuing review process of the trial taking place at their facilities.

These boards would be multiple centralized review boards (CRBs), which would be set up as regional review boards.

“Central review will use a single protocol and consent form, and monitor and evaluate adverse events on a global basis, eliminating many of the time-consuming steps for the local IRB,” stated the paper.

The use of a central IRB would not only improve oversight, but also reduce costs by allowing local IRBs to sidestep the initial review. The money saved would likely go toward the cost of monitoring trials, stated the paper.

To ensure that the new centralized process doesn’t delay trials, a system of “checks and balances would be put in place,” to ensure timely review. ASCO proposed a pilot program be started to centralize the review of clinical trials. If successful, the program could then be expanded, according to the paper.

Education and training
ASCO suggested that it should develop a curriculum that focuses on “proper conduct of human research and emphasizes ethically sound clinical research in the context of its annual meeting.”

Education, according to the paper, is critical to improving clinical trial oversights. All members of the research team and IRB should receive a “comprehensive education” on conducting research. This education should focus on ethics and proper scientific procedures, as well as federal and local regulations.

IRB members should receive training on reviewing protocols. Nonscientific IRB members should receive specially focused training to help them perform their jobs.

Informed consent
Organizations should focus on the informed consent process, not just the informed consent documents.

Federal oversight

1. The government should expand oversight to all trials and not just regulate those that are federally funded or covered by the Food and Drug Administration (FDA).

2. The FDA and OHRP should provide specific guidance for organizations that chose to use a CRB.

3. The government should “unify and streamline its regulations” for clinical trials oversight.

Providing resources and conflicts of interest
Organizations should be encouraged to give IRBs the money, resources, and the support needed to help members perform their jobs effectively. A set of standards should also be adopted to identify, manage, and eliminate conflicts of interest.
Ask the expert: Adverse events

This month’s experts are Tamara Norton-Smith, MT (ASCP), RAC, CCRA, president and senior consultant of Norton Audits Inc., in South Carolina and Adil Shamoo, PhD, a research scientist and professor at the University of Maryland, Baltimore.

Question #1: How can IRBs ensure that they don’t miss critical adverse event reports when they have so many to reports to examine? Are there any red flags that they should look for?

Answer: We do cause a lot of additional unnecessary work for IRBs sometimes, so I think what an IRB has to do up front is thoroughly define what it wants reported and to make sure that the principal investigators and study staff members at the facilities are well-trained in those policies. Currently, most IRBs are being inundated with adverse event reports that are not related to the medical device or the drug product, and they have to handle all that information. So it’s very important to make sure that the IRB, initially, defines what those adverse events are and what they want reported. Typically, those are the unexpected adverse events.

The other category one has to pay attention to is the serious adverse events. These are the ones that most people are concerned with. If they are minimal-risk adverse events, they are not as much of a concern, especially if they are expected. To me, if there is a death, a life-threatening problem, or a prolongation of a hospital stay, these are the kind of adverse events that require, in my opinion, serious review or study. This can hopefully prevent or reduce these types of adverse events in the future—which is the purpose of adverse event reporting.

Question #2: If the principal investigator reports an adverse event to the IRB and the IRB fails to report that adverse event to OHRP, is the principal investigator still responsible?

Answer: It is the principal investigator’s responsibility to report the adverse event to both the IRB and the Office of Rural Health Policy. The requirement is very different from the Food and Drug Administration’s (FDA) requirement because the burden with the FDA is on the sponsor—even though the principal investigator has to report to the IRB and sponsor. But the primary responsibility is put on the sponsor to report the adverse event to the FDA.

Question #3: Is there a difference between an adverse event and a toxicity?

Answer: I think a lot of times it really depends on the sponsor’s definition and its interpretation of that toxicity—what is expected, what is unexpected. I would err on the side of reporting instead of underreporting in this case. To clarify the issue, I would seek out some assistance from the sponsor to help you understand the toxicity and the level of that toxicity. Primarily, what I have seen is those toxicities are being reported as adverse events. But it really goes back to the protocol and what is defined—the classification, and what is known about the drug.

Editor’s note: The above questions were adapted from a recent audioconference sponsored by CTC called “Clinical Trials Adverse Events: How to Identify, Document, and Report.” To purchase a copy of the audioconference tape call our Customer Service Department at 800/650-6787.
Residual balances

regulations. Remember, it is critical for your organization to be consistent once it determines what residual funds can be used for, says Purner.

Training and auditing

Once you implement a solid policy regarding residual balances, it's important to train your staff to help them comply. “I’m a big advocate of the FDA’s [Good Clinical Practice] training,” says Purner. Residual balances training could be integrated in those training sessions, he says. Your organization should also have a means of auditing trials to pick up on potential problems in this area, says Purner. “There are a lot of organizations that I’m working with that are shooting for a goal of monitoring and auditing 10% of studies. Because of limited resources it’s hard to do the whole 10%, but that’s a good number to shoot for.”

When a study is closed, someone should look at

whether everything has been paid out
whether all the money came out of the research fund
any money that is leftover

This process can be critical for spotting not only deliberate, but also inadvertent billing errors, which might result in other billing violations—such as Medicare billing fraud. Often when subjects go into a hospital, they don’t get registered properly and as a result, their services may be billed to Medicare, instead of as part of the research study. By carefully monitoring this process, you can avert problems for your organization.

The study coordinator would be a good person to review study costs to ensure everything is being billed correctly.

“They have a close relationship to the study. They know the protocol really well,” says Purner. They can flag and rectify potential problems before faulty billing becomes an issue.