IRB ADVISOR

Your Practical Guide To Institutional Review Board Management

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Better understanding of UPs leads to fewer unnecessary IRB reports

UCLA's P&Ps provide best practice model

Human research protection offices have found that adopting policies and procedures regarding the reporting of unanticipated problems (UPs) has helped to reduce IRB busywork and improve the research community's understanding of when to report problems, experts say.

The key is to follow best practices through keeping policies up to date with regulatory changes, institutional requirements, and technological evolution. The University of California, Los Angeles (UCLA) recently updated its guidance and procedure for reporting UPs, which is a model for educating researchers and IRB staff about how to decide what is a UP and when to file an immediate and separate report.

UCLA's research protection office fine-tuned its UP reporting policy as the institution was seeking accreditation from the Association for the Accreditation of Human Research Protection

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Programs (AAHRPP) starting in 2008, says **Sharon Friend**, MS, CIP, director of the UCLA office of the human research protection program (OHRPP).

"First we let people know the changes were coming and gave them guidance," she says. "Then we changed everything we did, provided training, and alerted people to the drop-dead due date to follow the new procedures."

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Editorial Questions

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AAHRPP and later the Office of Human Research Protection (OHRP) provided guidance and definitions for unanticipated problems versus adverse events (AEs) and serious adverse events (SAEs). These materials are incorporated in UCLA's UP reporting policies and explained both in words and visually with diagrams. For instance, one bubble chart shows three separate bubbles for AEs, protocol violations, deviations and incidents, and updated study safety information. These three bubbles touch, but do not overlap, while a bigger bubble, labeled "unanticipated problems," overlaps a portion of each of the three smaller bubbles. *(See story about UCLA's guidance on UPs, page 75.)*

Rewriting and revamping

UCLA's change in UP and AE reporting parallels changes made at some other large research protection offices, where IRBs have seen a large decline in weekly reports, Friend and other experts say.

IRBs were inundated with serious adverse event reporting and with not-so-serious AE reporting prior to the mid-2000's. Investigators, at the urging of their sponsors, would report every adverse event as it occurred.

"We used to get literally boxes full of reports," says **Kathy McClelland**, CIP, research compliance director of Stanford University in Stanford, CA.

"Drug companies wanted their sites to report every little issue to the IRB immediately, and there are a lot of adverse events," McClelland adds.

"Now they understand that what's important to report are the unanticipated problems," she explains. "You still have to report adverse events and serious adverse events, and one of these could become an unanticipated problem, but it's a different mechanism for how these are reported."

The University of Utah in Salt Lake City adopted UP guidelines about six years ago, and the IRB office has continually refined and improved them, says **John Stillman**, CIP, IRB director.

An AAHRPP accreditation process was what led to the institution's extensive UP reporting changes, Stillman says.

"It has greatly improved our system; we focused our attention on unanticipated problems and our reporting caseload went down," Stillman says.

"We spend a lot of time looking at our report forms, standard operating procedures, and guidance," Stillman adds. "This is always something that can be challenging for IRBs and investigators."

Even research institutions that rarely have AE reports can benefit from new UP policies and procedures. It's not difficult to pull together information from OHRP, the FDA, and other websites, says **Susan A. Walsh**, PhD, RN, CCRN, IRB chair at Clayton State University in Morrow GA.

Although Clayton State University mostly has bio-behavioral and history research, the institution is starting to see an overall increase in research with some more diverse studies coming to the IRB. These have led the institution to revise and modify its Web page, bylaws, and policies and procedures, Walsh says.

"We're doing a lot of rewriting and revamping to meet the change," she adds.

UCLA's guidance for UPs provides best practice model

Clear definitions, easy links

The University of California Los Angeles (UCLA) recently updated its guidance on reporting unanticipated problems (UPs), adverse events (AEs), and other incidents in human subject research, providing a model for IRBs.

The 11-page guidance provides thorough definitions, examples, policy descriptions, and a diagram to provide investigators, IRB staff, and IRB members with clear instructions for filing reports. Titled "Guidance and Procedure: Post-Approval Reporting Requirements (PAR) for Investigators: Reporting of Unanticipated Problems, Including Adverse Events as well as Protocol Violations, Deviations and Incidents and the Reporting of Updated Study Safety Information," the guidance includes 19 links to regulatory and other information.

The UCLA policy offers this summary of the Office for Human Research Protection's (OHRP's) definition of unanticipated problems: "An event or outcome that meets the following criteria: 1) unexpected; 2) related or possibly related to participation in the research; and 3) places subjects or others at a greater risk of harm than was previously known or recognized."

The UCLA guidance for UPs features these main categories:

- general overview;
- definitions;
- policy;
- PI reporting responsibilities: adverse events, protocol violations, deviations, and incidents, and updated study safety information;
- IRB responsibilities and procedures;
- IRB reporting requirements;
- references and regulations.

For example, under AE reporting, the guidance asks investigators to report, within 10 working days, any internal or external adverse event that meets the criteria for an unanticipated problem; or that was expected and related but had a higher frequency of occurrence or higher level of severity; or that indicated a potential risk that requires notification of previously enrolled subjects; or that requires prompt reporting according to the protocol or study sponsor.

UCLA investigators also must report within three working days any internal subject deaths that occurred in the interventional study, were unexpected, and were related or possibly related to the research participation.

Under IRB Responsibilities and Procedures, the guidance outlines how the IRB is responsible for reviewing written reports of events and determining if they meet the criteria of an unanticipated problem involving risk to subjects and others. Reports of problems that could be UPs will be considered by the IRB, which could decide that a problem is a UP or that it requires no further action. Other possible actions by the IRB would include these:

- accepting an investigator's corrective action plan;
- modification of the research protocol, continuing review schedule, recruitment or informed consent;
- notifying current or previously enrolled subjects of the new information;
- observing the consent process through use of a consent monitor;
- requiring frequent status reports to the IRB;
- educational intervention for investigators and staff;
- referral to an on-site review;
- suspension of all or parts of the research;
- termination of the research. ■

AAHRPP and OHRP began to promote the term "unanticipated problems" in the mid-2000s, encouraging research sites to reduce their workload through more judicial reporting of AEs and other events. First, AAHRPP began to promote UP reporting as research organizations sought accreditation. Then OHRP published its Jan. 15, 2007, guidance on reviewing and reporting unanticipated problems, and this gave IRBs a framework for policies and procedures for reporting UPs, Friend and McClelland say.

OHRP has not tracked the trend of AE reporting but notes anecdotal evidence of an improvement.

"I have heard fewer complaints from IRBs about being inundated with adverse events reporting since OHRP issued its guidance," says **Kristina Borror**, PhD, director, division of compliance oversight, OHRP.

"However, we have not conducted a scientific sampling," she adds. "OHRP saw a steady increase in reporting in the years immediately following the 2007 guidance, but those reports also involved other things, including noncompliance, suspensions, and termination issues in addition to unanticipated problems."

"Unanticipated problem"

OHRP's guidance and use of the term "unanticipated problem" made it clear that not all adverse events needed to be reported immediately to the IRB, and it spelled out criteria for when an incident qualified as an unanticipated problem and needed to be reported. This change six years ago has helped reduce IRB workloads and has resulted in more efficient reporting and monitoring of adverse events, IRB experts say.

"Back in the days when we had paper files, some of our IRB chairs had files to review as high as they were, and all of these were adverse event reports," Friend says.

"If there was one occurrence of an adverse event for an investigational drug, then it would be reported for all of these different studies, and it was very frustrating for the IRB chairs," Friend recalls.

Still, there was some resistance to the program's change when policies about UPs first were introduced, she notes. The UCLA research community was not fond of the term "unanticipated problem" when UCLA first began to use it in guidance, Friend says.

These initial reservations disappeared after investigators began following the new UCLA guidance, policies and procedures for UPs and SAEs. The UCLA research community also became more invested in making changes when the human research protection program sought AAHRPP accreditation. AAHRPP had been encouraging IRBs to develop UP policies and procedures, Friend recalls.

"We did major educational outreach so people would understand a UP is more than an adverse event, and an adverse event might not be a UP," Friend says. "What we focus on here is post-approval reporting."

The result of the change has been a significant reduction in unnecessary AE reports, she adds.

"We made the change in 2008 and saw the reports drop right away, and there has been a continuing drop," Friend says. "People were thrilled."

The guidance's latest stage of evolution has been its integration in the IRB's online system. All paper references are gone, Friend notes.

Another change has been having researchers summarize all of the anticipated AEs and problems in one report at the time of continuing review, which gives the IRB context and the opportunity to note any trends, Friend says.

"What we needed was a summary of violations/deviations," she explains. "If something affects safety or the participant's welfare, we need to know right away, but if someone came in on the wrong day or missed an appointment, these are smaller things."

Before the UP change, there often was no distinction between small study deviations and major protocol violations or problems, she notes.

At Stanford University, all adverse events that do not qualify as unanticipated problems are reported at the study's continuing review, McClelland says.

When institutions have investigators report the expected AEs in one report, the IRB can see the big picture more clearly, noting any trends or greater-than-expected rate of any particular AE.

Although investigators still tend to report a little conservatively, the guidance has brought about the changes the IRB had intended, Friend says.

"People are very happy with this because they don't want to report every little thing to us," she says. "And the IRB is happy because they can focus on what's important." ■

Training Tips

Educational sessions provide gentle guidance

"Coffee and tea with the IRB"

A New Jersey IRB has found a way to build good will and bolster its reputation among researchers through an educational session of "Coffee and Tea with the IRB."

The Monmouth University IRB of West Long Branch, NJ, has begun holding mid-afternoon, intimate sessions in which investigators can meet with an IRB expert to discuss their concerns and receive tips for improving their IRB review applications. Like an English tea hour, the educational sessions also include fruit, cookies, and other light fare.

"When people have a full stomach or some sugar in their system, they're happier," says **Deborah N. Smith**, MA, assistant to the IRB and IACUC at Monmouth University.

Learning more about federal regulations is not anyone's idea of fun on a Wednesday afternoon, but a little tea and food helps, she adds.

"It's always friendly to sit down and have a cup of coffee with someone while going over everything they need help with," Smith says.

Smith came up with the idea after doing a Google search for IRBs and educational sessions and then discussing her findings with a peer and friend. Once she came up with the catchy title, she sent out a campus-wide email inviting researchers to bring their IRB applications for a preliminary review at the tea session.

The IRB has had several of these sessions, each with three or four investigators. Smith's plans are to make the "Coffee and Tea with the IRB" sessions a weekly occurrence in the fall. The weekly meetings might make it easier for researchers to fit the sessions into their schedules, she notes.

"Hopefully, we can get more people to come out to the sessions early in the semester," Smith says. "My goal is to alleviate the anxiety they have regarding the IRB process because it can be a positive experience for them."

The tea and training sessions last for up to 1.5 hours. Besides providing individualized IRB application support, Smith offers attendees education on a variety of regulatory topics, including these:

- wording and terminology in IRB application forms;
- a step-by-step guide to the review process from the risk-benefit ratio to informed consent;
- information about expedited review and how it's determined by the IRB;
- when research is exempt from an informed consent document requirement;
- basic elements of informed consent.

One researcher who joined Smith at a tea was in the idea phase of developing an oral history study. He was new to the university and discussed a negative experience he had with an IRB at this previous institution, she recalls.

Smith listened to his plans for the oral history project and told him that as long as he addressed everything in the IRB application he shouldn't have any problem with the process.

Since the study proposed to use an audio recording and to identify participants by name since participants in oral history projects typically do want their names included, the study would not be eligible for an exemption from informed consent, Smith says.

One of Smith's goals in starting the educational sessions was to put a friendly face on the IRB process and hopefully reduce the stigma associated with IRB review.

"We're friendly; we're here to help you and not just another loophole to go through," she says. "That's my goal every year: to keep that negative stigma away." ■

BEST PRACTICES SPOTLIGHT

Create lean, efficient, compliant SOPs

Expert keeps SOPs up-to-date

The IRB office at the University of Utah in Salt Lake City takes its standard operating procedures (SOPs) very seriously. The IRB even dedicates one highly experienced, part-time professional to make frequent revisions and improvements to the SOPs and guidance.

"She literally works with senior staff members to constantly review the SOPs and guidance and

continually update them," says **John Stillman**, CIP, IRB director.

In Stillman's 11 years with the IRB, it has been a struggle — especially early on — to develop the SOPs and make ongoing reviews of them. But when one of the most experienced members of the IRB office's 15-employee staff had to move across the country, the IRB made this an opportunity to secure the ideal person for the job of monitoring and updating SOPs and guidance. The employee was offered a job that could be done electronically and remotely since the entire human subjects protection program is automated and Web-based, Stillman explains.

"She has access on our website to this online system, and the way we've designed the system, it's relatively easy for her to do that in Indiana," he adds. "The fact that we're automated has helped us to maintain that relationship; she can Skype with us to attend senior staff meetings."

All suggested modifications to the SOPs and guidelines are reviewed by the associate director before they are approved and posted online, Stillman says.

The IRB's guidance and SOPs are extensive. The IRB's website has links to nearly 50 SOPs and even more guidance and policies. The SOPs are brief — mostly a couple of pages — and they are written in a numbered format. For instance, the SOP on training and education has two short paragraphs on policy and three numbered points on procedures, including IRB staff training, IRB member training, and investigator and study personnel training.

The goal of the SOPs and guidance is to have them communicate what should be seriously considered for any given policy and procedure, Stillman says.

The SOPs and guidance inform investigators, IRB staff, and others without dictating precise actions. This is to prevent deviations that violate policy. For instance, the SOP on IRB staff training says, simply, that "IRB staff will be encouraged to attend workshops and other educational opportunities focused on IRB functions and human subject research." If the policy were to specify sending staff to a specific workshop, then when that workshop suddenly becomes unavailable the IRB office could be in violation of its SOPs.

The IRB kept the SOPs written without explicit details for that reason, Stillman says.

"What we hope is that investigators will use the guidance more than the SOPs, so they can see these are the definitions and time frames," he says. "We generally drive them toward the guidance and, depending on the event, I might provide a link to the guidance in an email."

The guidance is more detailed and typically longer than the SOPs. The guidance contains a shaded box of "points to consider," which lists questions that will be asked in the study application, pertaining to this subject. The IRB's specific culture and expectations also are listed in the guidance.

For example, the four-page investigator guidance on recruitment methods states under the subhead "telephone calls" that the IRB generally does not allow cold calling in order to recruit participants. "If a researcher wishes to contact potential participants by telephone, a recruitment letter should be sent prior to the telephone call. The IRB strongly recommends that this letter include contact information for a potential participant to call in the event they chose to 'opt out' of forthcoming telephone contact," according to the guidance.

The IRB office uses the SOPs to make sure policies and procedures are correct and to make sure all rules are being followed, Stillman adds.

"We also use SOPs as a tool to help our investigators," he adds.

For instance, the three-page SOP on the definition of human subject research gives researchers the specific definitions under FDA and HHS regulations, as well as the University of Utah's policies regarding human subject research.

The IRB worked with a media consulting firm to improve its Web design based on data about which pages received the most hits, Stillman says.

"For years we had tons of information you could access, but it was so much information that it might have been overwhelming or difficult to find exactly what you wanted," he adds.

The Web design changes were geared toward making the site more interesting to users and to lead them to the answers they need, Stillman says. ■

Virtual IRB has quick turnaround for reviews

All board meetings are teleconferenced

The newly accredited MaGil IRB in Rockville, MD, has review process timelines that might seem impossible to other organizations, including a self-imposed deadline of four hours from the time an IRB review submission is made to the time it is seen by IRB members.

MaGil IRB's expedited reviews have a two-to-four-day turnaround time, while the full board reviews are completed within a week, says **Lisa Georgoff**, CIP, IRB administrator at MaGil IRB.

"The reason our CEO started this business is because he had been working in the industry and heard of problems of researchers dealing with large, bloated IRBs that were not customer friendly and took weeks to get back to them, and he thought we could do better," Georgoff says.

At the virtual IRB meetings, held twice a week, the board's five members discuss studies via a video conference. When a study requires an expertise the board does not possess, an outside consultant/expert is brought in, she adds.

The virtual meetings take place in the daytime, and one of the IRB's employees takes notes electronically, documenting all of these in the meeting minutes. On the IRB's electronic platform, a board member can make a comment or ask a question that is time-stamped, Georgoff explains.

"The system captures who reviewed it and when they reviewed it, so we have documentation that it was reviewed," she adds. "This increases the speed and efficiency by not having clients print something out and fax it or scan it and then making sure it gets to the right person's desk."

Everything about MaGil IRB is virtual from the submission forms to documents being made available virtually to IRB members and staff around the clock. Researchers can make submissions via computer, smartphone, tablet, or any other device with Internet access, Georgoff says.

"We have an investigator's handbook on our website," she says. "It has a checklist that helps to explain the submission process and includes definitions of risk and other terms."

The 21-page Investigator's Handbook includes a list of all required items for IRB review, definitions of protocol exceptions and deviations, special considerations for vulnerable populations, subject recruitment guidelines, and 23 sections in all. One example is the section on the IRB site visits: The handbook states that MaGil IRB may make site visits to the performance site or arrange for an outside agency to visit the site to obtain additional information about community attitudes, conditions surrounding the conduct of the research, and to make certain risks to subjects are minimized.

Other available checklists are for expedited reviews, exemptions, continuing reviews, initial protocol reviews, protocol deviations, and modification reviews.

The IRB, founded in 2009, completed a successful routine audit by the Food and Drug Administration (FDA) last year. In March 2013, the IRB was accredited through the Association for the Accreditation of Human Research Protection Programs (AAHRPP).

"One of our challenges is being the first virtual IRB and correcting misconceptions," Georgoff says. "We don't have face-to-face board meetings."

But the recent accreditation and last year's FDA audit show that the IRB's virtual work is compliant with all regulations, she notes.

Part of the IRB's best practices involves using an electronic platform that can monitor response time. Documents are signed electronically with signatures that are time-stamped and verifiable, Georgoff says.

"We can prove that on this date last year we did this audit and it was signed. Everything is time-stamped, verifiable, and trackable to ensure that it was in fact signed on a certain date on this computer by the person with this email address," she explains. "We can ensure that all signatures are compliant with regulations."

The IRB also conducts internal audits on a continual basis, reviewing policies and procedures to check for both quality and regulatory compliance.

"We submit test forms to make sure they're getting routed to where they should and to make sure everything is working the way it should," Georgoff says.

One of the IRB's major quality improvement measures was to hire a consulting firm to audit the organization, its standard operating procedures (SOPs), and to help the organization build an IRB that would be AAHRPP compliant, Georgoff says.

The consultants helped the organization improve the SOPs, all necessary items were included, she adds.

MaGil IRB's electronic system makes it possible to update SOPs immediately when new regulations or other changes occur, Georgoff notes.

"If we need to make a change to a form on our website, we can have it downloaded and submitted electronically very quickly," she adds. "So if it needs to be updated with new regulations, the form can be revised the day the regulatory change occurs."

The IRB's SOPs are extensive and searchable. In the table of contents there are links that take users to the correct section. There are no links to checklists and other forms that are referenced in the SOPs, but these can be found easily in another electronic folder, Georgoff says.

"We refer to the SOPs often," she adds. "We have periodic compliance checks where we go to a certain section and double check to make sure everything is working properly."

To ensure quality as well as speed, the IRB uses its internal checklists to verify that IRB review submission forms contain all the necessary information. If something is missing, an IRB specialist contacts the researcher.

"We manually look at the checklist and application, and if things are missing, we request the required documents," Georgoff says. ■

Sunshine Act will bring COI data headaches

Financial COI data will be made public

Get ready, IRBs — data collection for financial conflicts of interest (FCOIs) is about to get more complicated.

The Physician Payment Sunshine Act — a provision of the Affordable Care Act — will mean pharmaceutical, medical device, biological, and medical supply manufacturers will begin disclosing to CMS the payments they make to physicians and teaching hospitals (Medicare, Medicaid, Children's Health Insurance Programs Transparency Reports and Reporting of Physician Ownership or Investment Interests: 42 CFR Parts 402 and 403). CMS will then make the data available to the public at large. All payments will be made public, even if a product never received FDA approval, clearance, or licensure.

Beginning August 1st of this year, the industry will begin collecting information on payments made to physicians and teaching hospitals. The payment data will be submitted to CMS by the end of March 2014. After March 2014, CMS will alert affected teaching hospitals and individuals that the information is available for a 45-day review period and a 15-day reconciliation period. The information will then be made public in September 2014, repeated on a calendar year basis. It will include all payments or transfers of value made to a physician or teaching hospital.

All this information will likely cause massive headaches for IRBs, says **David Blake**, PhD, JD, vice president, chief compliance and privacy officer of Cedars-Sinai Medical Center in West Hollywood, CA.

"There's bound to be some discrepancy between what's getting publicly reported and what's being disclosed," he says. "There may also be confusion about payments to institutions that may benefit individuals and payments to individuals that may benefit institutions; and then how all of this might or might not actually affect research."

Blake gives an example scenario: An investigator could receive a federal grant for testing of a particular pharmaceutical company's new drug. The investigator might report that she has had no significant financial interests (SFIs) with this company for the previous 12 months (as required under the new Public Health Service COI regulations). CMS then may release data that the investigator received a consulting fee from the same pharmaceutical company but for a different drug, say 13 or 14 months prior. Since the information falls outside the required reporting timeline, the investigator had no specific obligation to report this consulting fee. With public reporting, however, it is quite possible that the previous financial interest could receive the attention of regulators, the media, or other body, questioning whether the non-disclosed previous payment could now compromise his or her research. Sorting out how to handle this and similar scenarios could prove to be a nightmare for a research institution.

Another issue that IRBs will face, Blake says, is being inundated with financial information that may not be material or relevant. "There will be a massive amount of data that might be inconsequential," he says. "IRBs will be flooded with information about very small payments that the IRBs may not care about, but they will have to sift through it all to see if individual researchers have any serious financial relationships amid all the small payment reported." For instance, a doctor may have

100 payments in the $25 range, but just a few larger payments. "They would still have to sort through all of the small-payment information to see if there's anything larger that could present a conflict," he says. At this point, it's not clear if CMS can deliver all the payment data provided to them by companies in a form that will be easily managed by research institutions.

Blake does not see the new regulations as necessarily the result of a demonstrated increase in the negative effects of financial relationship on clinical trials. "There's no clear evidence of an increased negative impact of outside financial relationships on clinical trials. I question whether things are much worse now that, say, 10 years ago," he says. Instead, he says, there is a marked increase in concern from politicians, regulators, the media, and some within academic medicine regarding possible negative effects.

"What has increased more recently is the management challenge in dealing with federal regulations, in particular dealing with the review of outside interests," he says. "There's an increased level of scrutiny at the federal and institutional level regarding these outside relationships. It's not necessarily the case that outside relationships necessarily adversely affected research — there's an understandable concern that it might happen. Whether the new regulatory requirements and increased public scrutiny are justified given the real possibility of adverse effects is the question."

The new regulatory requirements include updated SFI guidelines from the National Institutes of Health, which lowers the SFI threshold to $5,000 from $10,000. The regulations also define different types of SFIs. *(For more information, see box below.)*

In order to deal with the increased information from the Sunshine Act, Blake advises that IRBs develop a clear threshold for what they would consider to be a possible SFI, and clear policies for what information will need further evaluation. The IRB should also have a solid plan in place for managing possible FCOIs or SFIs, rather than just requiring further disclosure.

"A challenging issue is whether an outside interest can usually be best managed by simply requiring that the interest be further disclosed to research subject." Blake says. "I think that

Updated regulations clarify interests to be disclosed

In 2011, the National Institutes of Health released updated regulations to define significant financial interests. The regulations read as follows:

• "With regard to any publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds $5,000. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value. With regard to any non-publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds $5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest).

"Investigators also must disclose the occurrence of any reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available)."

• "With regard to any non-publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds $5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest)."

• "Investigators also must disclose the occurrence of any reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available)."

Read more about the regulations at http://www.gpo.gov/fdsys/pkg/FR-2011-08-25/pdf/2011-21633.pdf. ■

simply requiring further disclosures of interest are not in and of themselves an adequate management, partly because it's not clear what a research subject would make of those disclosures. I would think for a layperson — especially if they are suffering some condition and the experimental treatment is showing promise — it would be hard to determine if outside interest disclosed to me is a good thing or bad thing."

At Cedars-Sinai Medical Center, the IRBs have a separate committee to review outside interests. Some financial interests require nothing more than a simple disclosure in the consent process, while greater interests could require the investigator be excluded from certain areas of the study, such as subject recruitment or data analysis and review. "The guidelines are spelled out in detail in policies and in the research COI committee that monitors these relationships," Blake says. ■

For one IRB, splitting up is easy to do

Smaller boards bring smaller workloads

For IRBs at mid-sized institutions, monthly meetings can go for hours and involve many protocols. This can be very time-consuming and cumbersome for IRB members and investigators alike. Protocol discussions may not get the time they need, and members simply may not have enough time to review all the agenda items.

The human research protection program and IRB at Wake Forest School of Medicine in Winston-Salem, NC, was no exception. While the average 45-day turnaround for full board review was right at the national average, the board's productivity was not where it could have been. They had four boards with an average of 18 members who met once per month for four or more hours, and usually had an agenda of 16 to 20 protocol actions to consider. Many IRB members did not have the time to review the full agenda before meetings. Maintaining the quorum of 10 people for each meeting was often difficult, as members were sometimes late from seeing patients or were paged away for emergencies. Tabled studies had a month-long wait before reconsideration. Wake Forest IRB leaders decided to look for a more practical solution.

Productivity inspiration

"When you have agendas that are sometimes 16 to 20 protocols or actions long, the meetings were often three to four hours long and we were concerned because if board members were paged away, they would miss things later in the meeting," says **Joseph Andrews**, PhD, CIP, director of the Wake Forest School of Medicine IRB. Developing questions and writing minutes from four-hour meetings were also particularly cumbersome.

Andrews and colleagues looked to commercial IRBs for productivity inspiration. "One question we had was how they were able to be so efficient and have high-quality reviews," he says.

After careful review, they decided to split the four existing IRB boards into eight smaller boards that would meet every two weeks instead of once per month. Protocols are divided among the smaller boards so that each has only four or five protocols to review in much shorter, one-hour meetings. Boards meet on days that accommodate everyone's availability. Meeting minutes are shorter and far less cumbersome, and everyone has time to fully review all agenda actions prior to meetings.

"Board members are able to more easily look at and retain the information and ask more thoughtful questions with four of five items than with 16 items," Andrews says. "Faculty on the board have been extremely supportive of the model because they don't have to block the whole afternoon out for the meeting — now they can go back and see patients or teach a class after the meetings."

The Wake Forest administration granted the IRB a four-month pilot to test the new model. The idea was met with some concerns, including whether board members would agree to two meetings per month rather than one, and that fewer experts would be on each board.

"I think the staff were eager to try it," Andrews says. There were some concerns from staff, but "once they got the first set of [meeting] minutes in and there were only four or five items to note, it was such a relief from

the 16 or 17 actions they had before."

To form the new boards, the vice chairs were promoted to chair positions for the four new ones. IRB board members were given copies of the schedules of the new boards and selected their top three choices based on their individual schedules. Members were assigned boards based on their availability. Those who had scheduling conflicts with all the new meeting dates were offered alternate positions. Overall, attendance has been increased to 100%, or close to it, for all meetings.

The smaller boards also solved issues with facilities. Squeezing 15 to 20 board members in one room for meetings was a challenge, and the room did not have much audio-visual equipment. "We had a hard time finding a room to accommodate everyone comfortably," says **Brian Moore**, MS, CIP, assistant director of the Wake Forest IRB. "We would have a lot of tables set up with 15-20 staff members in the room. The facilities didn't allow for video and teleconference in rooms that size. By splitting up the boards, we were able to put them in a more hospitable area with audio-video and more equipment." For those who are unable to attend in person, they can now be present via telephone or video conference. "We can now get close to 100% attendance," Moore says.

Turnaround time

Turnaround time for protocol approval has decreased by nearly 50%, Andrews says. And with shorter meetings and fewer protocol actions in each, board members are able to have investigators present in person or by remote conference to further explain a protocol and clarify and questions. "Previously, with heavy agendas and a long meeting it would throw everything behind when the [investigators] came to the meetings. With the new model, they can call in and answer questions about the protocol, or pop into the room and talk, and with only four or five agenda items, we don't fall behind." Discussion time for each item has increased 33%, he says.

And the IRB was able to implement the model without any additional costs to the university.

"We haven't changed the ratio of staffing and no additional resources were required from the institution to do this," Moore says. "There was no cost added, but a lot of value was added."

"Many institutions are facing budget crunches, so increasing costs by ramping up staff members are prohibitive in some cases," Andrews says. "We used the same four-analyst mode, and now each analyst is assigned to two different boards. Workload has gone down because instead of having 16 actions and four-hour sets of minutes, there are four items to write up and time for questions to send back to investigators. We haven't had any negative impacts at all." ■

CNE/CME OBJECTIVES & INSTRUCTIONS

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

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

Physicians and nurses participate in this continuing education program and earn credit for this activity by following these instructions.

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5. Once the completed evaluation is received, a credit letter will be e-mailed to you instantly. ■

COMING IN FUTURE MONTHS

- IRB's streamlining efforts involve "unchecking the box" for FWA
- Clear up misconceptions about when IC is needed
- HRP program's efficiency and speed greatly improve
- Whatever happened to Common Rule changes?

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CNE/CME QUESTIONS

1. Which of the following is the criteria of what constitutes an "unanticipated problem?"
   A. An event or outcome that is unexpected
   B. An event or outcome that is related or possibly related to participation in the research
   C. An event or outcome that places subjects or others at a greater risk of harm than was previously known or recognized
   D. All of the above

2. Which of the following would be a good reason for keeping standard operating procedures short and lacking in specific instructions?
   A. Short and more general SOPs do not need as much updating
   B. This meshes with federal regulatory guidance
   C. SOPs with general framework and few specifics are less likely to cause an IRB to be found in noncompliance with its own SOPs
   D. None of the above

3. Federal regulators and accreditation organizations will not approve an IRB that operates completely virtually with teleconference meetings instead of face-to-face board meetings.
   A. True
   B. False

4. According to David Blake, PhD, JD, vice president, chief compliance and privacy officer of Cedars-Sinai Medical Center, which of the following is a way for IRBs to handle the upcoming increase in COI data?
   A. Requiring further disclosures of interest in the consent process
   B. Create a clear threshold for what would be considered SFI
   C. Remove the investigator from the study completely
   D. None of the above

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Lee Landenberger
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