IRB ADVISOR

Your Practical Guide To Institutional Review Board Management

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Special Report: Streamlining IRB Process

Experts: Saving time while improving review quality is top priority

"Unchecking the box" is a good start

Research programs and IRBs across the nation increasingly are focusing on streamlining their human subjects research programs. One change that has grown over the past decade involves "unchecking the box" on the Federalwide Assurance (FWA).

According to recent data from the Office for Human Research Protection (OHRP), 37% of research organizations uncheck the box on all subparts (A, B, C, D) and another 32% unchecked the box on all but subpart A.[1]

This trend has its own organization, called the Flexibility Coalition, which was started in 2011 by the University of Southern California in Los Angeles. More than 50 research organizations, including the Association for the Accreditation of Human Research Protection Programs (AAHRPP), have joined the coalition. AAHRPP reports that 51% of AAHRPP-accredited organizations had unchecked the FWA box and another 22% checked only the box applying to Subpart A. The trend of institutions unchecking the box has progressed over the past 15 years. In the 1990s, more than three-quarters of institutions checked the box.[1,2]

The Flexibility Coalition's stated goal is to identify ways research institutions can implement flexibility without harming human subject protection. By unchecking the box on Federalwide Assurance for the Protection of Human Subjects, institutions can limit the FWA scope to

Editor's note: The August 2013 issue of IRB Advisor *is focusing on the national trend among IRBs and research institutions to look for ways to improve efficiency and quality, reduce regulatory burden and unnecessary documentation, and, essentially, streamline their human subjects research programs. In this issue, the cover story focuses on the growing trend of "unchecking the box" for Federalwide Assurance. Additional articles focus on ways to improve informed consent, expedited reviews, reducing review turnaround time, and hiring IRB liaisons.*

federally funded research. Unfunded research projects have the same human subjects protection, but the unchecked box gives an institution more flexibility in how it handles these studies.

"We unchecked the box six or seven years ago," says **Susan L. Rose**, executive director of the office for the protection of research subjects at the University of Southern California (USC).

"Unchecking the box had never crossed my mind, and then I heard about it at an AAHRPP meeting," Rose recalls. "We did it here and it has been a life changer."

The change has impacted hundreds of studies at USC, including both biomedical and social-behavioral studies. One priority in making the change has been to emphasize to researchers that the level of human subjects protection for research that is handled through the flexibility changes must be equivalent to protections for all federally funded research, Rose says. *(See excerpt from USC's flexibility policy, page 87.)*

One of the goals of unchecking the box and improving flexibility is to avoid having investigators report trivial issues when they occur in a study that is not federally funded and is of minimal risk. For example, if a participant answering questions through an electronic questionnaire were to have dry eyes from staring at the computer screen, that would have been reported prior to "unchecking the box," Rose explains.

"It takes a huge amount of paperwork to report everything," Rose adds. "This allows flexibility to be applied to those projects that are not federally funded and have no risk."

USC's flexibility policy allows for exceptions and also states that it creates exempt categories 7 and 8 for projects that do not conform to a specific exempt category in the regulations (45 CFR 46), and it allows for two-year approvals for nonexempt unfunded projects that are not FDA-regulated and involve minimal risk.

"We have a huge list of items that may be flexed and items that may not be flexed, and if funding changes during the year and someone receives federal funding, we need to know immediately," Rose says. "No one has violated that."

Streamlining research and unchecking the box are trends that are slowly growing in the IRB world, says **Lori Roesch**, CIM, CIP, manager of the research subject protection program at Aurora Health Care Inc. of Milwaukee.

Roesch recalls first learning about the drive for flexibility in research through AAHRPP.

"I think it is the wave of the future," she says. "As we talk about it more at AAHRPP conferences, more people will get the word out there, and the Flexibility Coalition will help."

"I saw how you could improve your program through that flexibility," Roesch says. "In August 2009, we had a discussion about unchecking the box; I recommended we no longer check the box

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and limit OHRP's jurisdiction to studies that have federal funds."

When Roesch presented this change to the organization's leadership, she talked about how many institutions were moving in that direction and that AAHRPP, which had accredited Aurora Health Care, also supported flexibility.

"They agreed to move forward with the recommendation," Roesch says. "We decided to apply this only to studies that don't leave our organization and which will be maintained here."

Aurora Health Care recently joined the Flexibility Coalition, which provides tips on flexibility and streamlining, she says.

"I'm looking forward to hearing other ways we can use flexibility while having protections in place for subjects," Roesch says. "We have to make sure we're applying equivalent protections, but the flexibility of unchecking the box allows you to do it in ways that are not as proscribed as the regulations are."

One flexibility project Aurora Health Care started a year ago involved streamlining residents' medical record retrospective reviews. Before unchecking the box, the organization would have had to handle these studies through the formal expedited review process, Roesch notes.

"What we've done is used flexibility to provide our researchers with a very streamlined application and review process that we call a category 10 for expedited review," she explains. "Studies that meet certain parameters can be expedited and informed consent is waived."

This change has made the submission process simpler and more straightforward for these retrospective studies, and it's helped the IRB turn around requests much more quickly, Roesch adds. *(See story on IRB efficiency measures, page 88.)*

"Researchers are pleased with how quickly we can turn these around and how streamlined the application process is," she says.

Flexibility and streamlining have become such an integral part of Stanford University's research enterprise that the university has named 2013 as the "Year of Streamlining." The institution's research leadership has made streamlining a priority for the entire research enterprise, and the goal is stated clearly on its website. Its intention is to cut back on unnecessary activities, says **Kathy McClelland**, CIP, research compliance director of Stanford University in Stanford, CA.

Stanford University unchecked the box a couple of years ago and has continued to find new ways to streamline its research operations since then, she says.

"We unchecked the box and are streamlining operations so we can concentrate on the higher-risk studies, putting our resources where it's most important," McClelland explains.

For example, Stanford no longer requires annual continuing reviews for around 1,000 active, nonmedical studies, she says.

"Instead of having them fill out the continuing review form annually, we send a communication telling them that if they haven't made any changes or haven't received any new federal funding then they don't have to file anything with us," McClelland adds. "We do this for three years; then after three years if they're still doing their study they will need to renew at that time."

This frees up time for both the IRB and

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USC's flexibility policy has these exclusions

Funding is factor

The University of Southern California in Los Angeles allows flexibility in its research protection program through limiting the scope of its Federalwide Assurance (FWA) to federally funded research that is of minimal or no risk. These studies are given similar protections to funded studies. Nine mandatory exclusions, listed below, apply:

- funding (exceptions may apply for non-federally funded research);
- no-cost extensions;
- projects where a student is paid/supported from a federal training grant or otherwise paid/supported directly from the faculty advisor's federal funds;
- federal sponsorship, including federal training grants;
- studies with FDA-regulated components;
- studies with contractual obligations or restrictions that preclude eligibility in this policy;
- studies with clinical interventions;
- studies using prisoners as subjects;
- studies seeking or obtaining Certificates of Confidentiality. ■

investigators. The dean of research has a goal of helping investigators free up their time so they can do their research as opposed to doing time-consuming paperwork, she says.

"It's a win-win for the IRB and researchers and saves some staff time, as well," McClelland says. "We started this one and a half years ago and it's working very well."

To ensure that investigators remain compliant during this three-year lag, the compliance office randomly audits study sites, asking investigators to send in their last three signed informed consent forms and inquires about their funding sources, she adds.

Another streamlining change was made for retrospective chart reviews. When investigators are not receiving federal funding to look at existing medical records to find trends for improving treatment, they also are eligible for a three-year IRB approval, McClelland says.

"That will save a lot of people's time so they won't have to renew annually," she says. "We've created a new chart review application form, which is very much abbreviated from our regular, 22-page form down to six pages."

The regular form asks questions about investigational drugs and devices, and this information is not pertinent to a chart review, she adds.

Unchecking the box gives research institutions the flexibility of categorizing more research as exempt, Rose notes.

For example, USC has a flex policy that lists these examples of non-funded research that might be exempt: online surveys, in-person focus groups, behavioral games, studies requiring no-risk performance tasks, medical record reviews, data analysis from court records, and studies using eye-tracking technology.

"IRBs are overloaded, so having their attention focused on things that cause risk is a life-changer," Rose says. "We haven't measured how much time is saved, but we know it allows more attention to be paid to [higher-risk] studies."

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Special Report: Streamlining IRB Process

IRBs may improve efficiency with these tips

Improve expedited review process

Research institutions nationwide continue to look for ways to improve quality while eliminating redundancy, regulatory creep, and inefficiencies. The key to success is flexibility and considering changes in any type of process that is not working as efficiently as possible, experts say.

Areas that can be addressed for improvements and greater efficiencies are varied, ranging from revamping the board to improving the way expedited reviews are handled. Here are some ideas:

• **Revamping the IRB board:** For instance, some IRBs have found that adding more ethics boards can help reduce the time from protocol submission to an IRB decision. But one IRB has found that making the opposite change also can improve operations. The office of research compliance and biosafety at Texas A&M University (TAMU) in College Station condensed its IRB from four boards to one board to improve efficiency, says **Catherine L. Higgins**, PhD, IRB manager.

"We also increased the IRB's membership, and that seems to work quite well," she says. "We have 16 IRB members, and we are adding 10 more."

The institution made the change to one board last year with the goal of going back to basics while also engaging more IRB member enthusiasm and commitment, Higgins explains.

"One board makes sense for us; IRB members meet once a month for about five hours," she says. "The IRB meeting discussions are extremely interesting, and the group has become more vibrant and exciting over the past year."

The IRB has close to 2,500 active studies, and the number of submissions per month doubled from 150 to 300 after the consolidation of boards. Also, the IRB's processing time for submissions dropped from 17 days to two days in that same period of time, Higgins says.

• **Using IRB liaisons:** Credit for the improved processing time at TAMU is shared by several initiatives, including the board consolidation. One of the biggest contributors to the improvement is the IRB's adoption of an electronic submission system and the creation of IRB staff liaisons for pre-reviewing studies and working with