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Ethics at the cost of research?

Educational efforts aim to ease the growing tension between researchers and the ethics boards that review their work.

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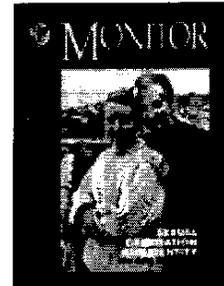
Few topics elicit more emotion from psychology researchers than the mention of three simple letters: IRB.

Institutional review boards--those federally mandated ethics committees that evaluate all federally funded and most institutionally sponsored research conducted with humans--are often seen by researchers as synonymous with delays, unreasonable requests and seemingly capricious requirements. Behavioral and social science researchers' major complaint is that many IRBs subject them to regulations written and interpreted through a biomedical lens, with little recognition of the major differences between medical research and what they do. This results, in their view, in unnecessary delays and constraints that impede research but do little to enhance the protection of research participants.

To help facilitate researcher and IRB interactions, APA and other groups are seeking to better educate IRBs about social and behavioral sciences research as well as to teach researchers how they can work more effectively with their IRBs.

"We need to move in a direction where we all come to value issues involved in human protections," says psychologist Michael Fendrich, PhD, a researcher and chair of the social and behavioral sciences IRB at the University of Illinois, Chicago. "We need to see it as a gain for our research--not a burden--that makes the research better."

At the same time, he admits, IRBs and IRB administrators have a lot to learn about balancing a need for heightened scrutiny--based in large part on several biomedical research disasters that have led to temporary suspension of some human



[Regulations on research with humans in flux](#)

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*-Michael Fendrich
University of
Illinois, Chicago*

research programs--with a realistic view of the risk level posed by the research.

Local interpretations

Although the condemnation of IRBs can get quite strong, even the most vitriolic researcher agrees that, in theory, IRBs serve an important role in ensuring ethical research and maintaining public confidence in the research system.

"I have had some wonderful experiences with IRBs," says Pennsylvania State University developmental psychologist Sheri Berenbaum, PhD, who deals with multiple IRBs because her work spans several institutions. "Penn State's IRB, for example, is a model of how an IRB should operate. [Its members] hold in mind the question of what the risk is to the subject and everything they ask ties back to minimizing that risk. They've recently noticed a problem that I overlooked and I'm grateful for that oversight."

Problems arise, says Berenbaum, when IRBs either don't understand the research they're reviewing so they apply regulations without carefully considering the consequences, or they lose sight of their duty to protect study participants.

That can happen because the federal government has given IRBs incredible latitude in interpreting its regulations for research. This flexibility allows IRBs to reflect local values. It also makes IRB review extremely variable from one institution to another.

"IRBs are like school districts, enforcing local ideas of what's acceptable and what's unacceptable," says Temple University psychologist Nora Newcombe, PhD, president of APA's Div. 7 (Developmental). So, people like Berenbaum, who need to get approval from several IRBs, may have to modify their research protocols depending on the institution. In fact, she has to design a different consent form for each medical center where she recruits participants. In addition, every participant signs two consent forms because each medical center interprets the rules differently and is not content to accept the form approved by Penn State's IRB.

As it is, most psychologists believe the language in consent forms has become so cumbersome, many participants don't read them thoroughly. Even seemingly harmless studies of spatial ability or

memory often have consent forms as long as two pages of small type.

"We have to include every possible scenario that could come up," says Northwestern developmental psychologist David Uttal, PhD. "The result is, in our desire to protect the university and people's rights and safety, we may actually be doing people a disservice because we are forced to overwhelm them with a very large number of details. People's truly informed consent is not served by this process."

And because regulations are based on a biomedical model, much of the "boilerplate" wording is not appropriate for behavioral research. For example, many researchers complain that they have to include wording informing people about "alternative procedures or courses of treatment" to participating in the study. This implies that the purpose of the research is therapeutic.

"But in most behavioral research the alternative to participating is simply not participating," says Merry Bullock, PhD, APA's assistant executive director for science. "Unless not participating is socially awkward--for example, all the kids in a class participate and not doing so would be embarrassing--or unless participation is a course requirement, there is no meaningful alternative."

Educating IRBs...

APA hopes to help with some of these problems by creating educational documents that could help IRBs better understand the goals and procedures of behavioral research and how federal regulations apply to that work. APA's Board of Scientific Affairs (BSA) has made this issue a top priority this year and hopes to have something to send out to IRBs by fall. "We need to help them think of procedures that are less taxing for them and for us," says University of Rochester social psychologist Harry T. Reis, PhD, chair of BSA.

In addition, APA hopes to help IRBs better assess the magnitude as well as the probability of harm in typical behavioral research protocols.

"The risks associated with most psychology research are minimal," says Bullock. "But an IRB that views research from a medical research perspective may not appropriately evaluate low-risk behavioral studies."

Along with educating IRBs about the general issue of how the bulk of behavioral research differs from biomedical studies, APA will also address issues specific to certain types of research. For example, developmental researchers have run into problems with state "mandatory reporting" laws related to child abuse, which require health professionals--including psychologists--to report any suspected abuse among children they contact. Most states distinguish between research psychologists and clinicians by stating that only "licensed" health professionals fall under this law. But some IRBs have applied the law to research psychologists working with children.

Northwestern's Uttal is one of them. He's been conducting research on children's spatial learning for the past eight years, with only slight changes to his research protocol. Last year he sent a revision to his IRB, expecting little trouble. But a problem arose when an IRB staff person inserted language into Uttal's informed consent form designating him a "mandatory informer."

Illinois law designates any "registered psychologist" a mandatory informer, and Uttal's university attorney interpreted that to mean any psychologist working with children. "Psychologists have to know the limits of their expertise and I know that there is nothing in my training as a research psychologist that would make me qualified to identify child abuse any more than a lay person," says Uttal. "Putting something like this into my consent form damages my credibility with parents and makes my benign research seem risky."

That's what he explained to his IRB in an appeal to its request and, after several weeks of discussions, his appeal was accepted. It was a learning experience for all involved, says Uttal.

APA hopes that it can help prevent problems like Uttal's in the future by creating educational materials explaining the distinction between research and practice in psychology.

...and researchers too

Most IRBs will welcome the education, says Virginia Commonwealth University psychologist Tom Eissenberg, PhD, who sits on his own IRB. He looks at situations like Uttal's as "opportunities for education." The key is for researchers to

understand the regulations well enough to know when they can protest a ruling and when they can't.

"The regulations clearly state that IRBs must give researchers an opportunity to respond," says the University of Illinois' Fendrich. "So if researchers don't agree with IRB decisions, it's important that they challenge those decisions. In my view, not enough of us do that."

On the issue of overly long consent forms, for example, federal regulations allow an IRB to waive any and all elements of consent under certain circumstances, says Eissenberg.

"This is an obvious case where the investigator is right to say, 'We're not doing the right thing to have a long consent form--this language is extraneous and it harms my subjects for me to have it in there,'" says Eissenberg.

Funding agencies are increasingly mandating that researchers better understand the federal regulations for the protection of human participants in research. For the past year, the National Institutes of Health (NIH) has required all personnel involved in NIH-funded research with humans to pass a course on ethics and human subjects research, and the National Science Foundation is looking into the matter.

So far, most of the courses available are oriented toward biomedical research, although that is beginning to change. In particular, APA is working with a group of researchers and IRB administrators--coordinated by Lorna Hicks at Duke University--to develop a tutorial that specifically addresses social and behavioral research. They hope to have a usable product by the end of this year.

In the meantime, the regulation of human subjects research continues to evolve (see sidebar, page 39) as public fears of safety and institutional fears of legal problems mount. More education on all fronts is likely the best long-term solution. For researchers, that means taking the time to question rulings they disagree with, even if it delays their research further. And it can only help if they pay their dues and sit on an IRB for a time, says Eissenberg. His own experience has changed his attitude dramatically.

"I viewed the IRB more as a hurdle to get over

rather than a way of helping me improve my research," he says. "It's easy to become complacent about the activities that you conduct in day-to-day research life. Outside members of the scientific community aren't doing what you do every day and might see the risks differently."

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