

# IRB ADVISOR

*Your Practical Guide To  
Institutional Review  
Board Management*

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## AAHRPP: Human protections programs have made great strides

*Bioethics, genetic research also addressed at annual conference*

Once deemed "a mess," IRBs have shown huge improvement in the last decade, says Association for the Accreditation of Human Research Protection Programs (AAHRPP) CEO Marjorie Speers, PhD.

Bioethics, global expansion, and the state of the organization were also big topics at AAHRPP's conference in Miami, April 3rd-5th.

Outgoing AAHRPP CEO Speers took time to reflect on changes to the IRB system and to AAHRPP itself. Around the time of AAHRPP's formation in 2001, IRBs were "a mess," Speers says, dealing with a host of noncompliance issues. "In the past, IRBs did everything they could to stay under the radar," she says. "IRBs had a negative image and did not want to make it worse by dealing with noncompliance."

The organization formed as a way to advise organizations and government on human research protections. Today, Speers says, human research protection programs are the norm, and the number of governmental noncompliance warnings has plummeted.

"We have accomplished three things: knowledge, communication and confidence," Speers says. "There has been a tremendous growth in confidence in research organizations and the research community in general."

Communication among research organizations is growing. "University systems are accredited and can form partnerships and work together in ways they could not previously," Speers says.

IRBs have been more willing to take risks and try new things to promote human subject protections, including the growth of IRB collaborations and consortia. "We can push the systems in ways we couldn't before," Speers says.

The current IRB system is outdated and doesn't meet the needs of IRBs today, Speers says. "That is what will be the challenge in the next decade or so," she says. There have been "dramatic changes"

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in larger, independent IRBs in the last several years, including mergers and acquisitions. “[Independent IRBs] will be sustainable for a long time — they are owned by companies, which guarantees sustainability,” Speers says. “There will be fewer [independent IRBs] in the next three years, but they will be larger and

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#### Editorial Questions

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capable of reviewing a wide range of research.”

“We have only just dabbled” in collaborations, Speers says. “Collaborations will grow and become stronger.”

AAHRPP is also seeing international growth and is expanding into Europe, Asia, and the Middle East. China and India are seeing major growth in research — in fact, Speers says, China is expected to surpass the U.S. in the number of scientific, peer-reviewed papers published. “We are seeing growth in other countries because they are making financial investments in their scientists,” she says.

## The gap between research and bioethics

Trying to define how to bridge the gap between bioethics and research is not simple, says Sergio Litewka, MD, MPH, international director, University of Miami Ethics Programs and CITI Program. “Sometimes this bridge is very frail and is over more than just a gap,” he says.

Sometimes, Litewka says, the gap is related to differences in personality between researchers and bioethicists. Ethicists, he says, look at the means in which results are found, while researchers may simply want results. “Bioethicists are thinkers, others are doers,” Litewka says.

Bioethical concerns include justice, cultural sensitivity, and standard of care:

- **Justice:** This is a very complex issue, according to Litewka. “Who will benefit, and who will be responsible for delivering the benefit? Who will be entitled to receive it, and when? Most international guidance confuses the issue and tries to be too politically correct,” he says. Other justice considerations include finding an acceptable definition of exploitation, and determining who should decide what post-trial benefits should be shared with whom in the community.

- **Cultural sensitivity:** “This is also a very delicate issue,” Litewka says. “Doing research multilaterally means different ways to communicate same idea. Is it ethical to accept moral values exclusively related to cultural norms or habits from a particular society, even when these habits might harm minorities or ethnic groups?” One size of care does not fit all, he says.

- **Standard of care:** What is the best established method of caring for research

subjects? Should the standard of care be tailored to a community's established ideas?

Standard of care is also related to what Litewka refers to as "ethical imperialism." Is it, he asks, ethical to accept moral values exclusively related to cultural norms or habits, even when it might harm other groups? Which cultural values should be followed? "The danger is when we accept blindly situations that could harm other people," Litewka says. "We do not harm and do not kill."

Challenges for researchers and subjects in developing countries include:

- weak regulations and enforcement of current regulations;
- research ethics committees that may be inadequately funded or with very little expertise in some particular areas;
- economic disparities and access to the healthcare system;
- insufficient or absent policies for research ethics education;
- ideological tensions;
- lack of agreement in critical issues.

Findings of the International Panel of the Presidential Commission for the Study of Bioethical Issues 2011 suggest the following areas for improvement:

- Increasing accountability: Improve through public access.
- Helping those who are harmed as a result of research participation.
- Respecting equivalent protections of international partners.
- Promoting a culture of responsibility.
- Evaluating site selection and the justification for chose study design.
- Engaging communities at all levels of research.

"Research with humans is a multinational enterprise in need of interdependent solutions," he says. "Site accreditation throughout a set of accepted global standards is a considerable step towards the protection of subjects and the integrity of research."

### **Following the Common Rule**

A study presented by Paul S. Appelbaum, MD, Dollaro Professor of psychiatry, medicine, and law at Columbia University in New York City, suggests that IRBs may not be discussing Common Rule requirements as they should.

To get to the bottom of things, Appelbaum

and colleagues observed 10 IRBs around the country by recording meetings and performing interviews with 263 IRB members. In 20 different meetings the researchers attended, 114 protocols were reviewed. After poring over hours of transcribed interviews and meetings, the researchers found that IRBs frequently failed to discuss many of the human subjects protection criteria mandated by the Common Rule:

- Equitable recruitment of research subjects was not discussed 80% of the time, and most discussions involved exclusion of pregnant women.
- Vulnerable populations were not discussed 50% of the time.
- Safety monitoring was not discussed 73% of the time.
- Risk minimization left out 37% of the time.

Appelbaum conceded that the study data do not capture the work that is done in preparation for meetings. "But what these data do capture are aspects of what goes on inside the room and how it might differ from the regulatory or administrative vision of what should be going on," he said.

Appelbaum also reported high numbers of members among the interviewed IRBs — usually around 15, with one study reporting a high of 44. Federal regulations only require five. "IRBs are filling the rooms of meetings with many more people than are required. This may be a good thing, it may not be a good thing ... There may be too many people around the table."

*(For more details on this study, see the related article on page 56.)*

### **Paternalism vs. partnership in genetic research**

Research subjects want greater involvement in the study process — and in what may later happen to any tissue or other biological samples they may give. "Leaving patients out of the process misses out on a lot of good information," says Rebecca Dresser, JD, professor of law and ethics in medicine at Washington University in St. Louis.

For the most part, researchers lack experience in being research subjects and tend to only see things from one perspective. "We all have our professional glasses on and see things through a different lens than subjects do," Dresser says.

There is no particular role for a layperson in research, she says. More and more, members

of the public are becoming interested in moving research forward and getting help for themselves and others — and represent subjects' interests, feelings, and issues in the course of research. "The traditional [research] model is under pressure, and nowhere more than in the genetics field," Dresser says. "There is a push to look at subjects for ethical guidelines and see them as true partners in research."

Research subjects, Dresser says, want to be respected as partners in research and seen as more than just patients or passive providers of tissue samples. "Participants view themselves as having an ongoing stake in research and want to be informed of further use of their samples," Dresser says.

In a University of Washington focus group, 90% of participants said it is important to be asked for permission for further use of samples and for permission to share de-identified data with other investigators.

A vast majority, Dresser said, wanted to know about individual results, including health risks "even if there was nothing they could do about them." Participants also wanted to know information relevant to family risk, reproductive decisions, environmental risks, life and financial planning, and potential future research. "People just want to know what could be wrong with any tissue samples," Dresser says.

There is also the question of whether participants are adequately informed of the risks and benefits of a study in order to be a partner in research. "Some will overestimate benefits of genetic research. Some will fail to realize potential harms, such as the stress of finding out genetic issues, and the effects it could have on insurance," Dresser says. These are issues that can be addressed through counseling and education, she says, rather than just withholding the information. Many people may be unwilling to participate in research if they don't have control over what may happen to their samples later, and could result in a decrease in participants. And there is some justified paternalism, Dresser says. "We don't want it [research] driven by overhype and blind consumerism."

"Researchers can benefit from listening to input from subjects who have been through the process and have that perspective researchers may not have," she says. ■

## SWAT! project provides support to investigators

*IRB's best practice is popular with PIs*

IRBs searching for highly effective ways to improve protocol submissions and enhance education and training efforts might check out the SWAT! program at Washington University in St. Louis.

SWAT! — Staff With Answers Today! — provides just-in-time education and an ongoing training program for IRB and research staff. Seven members of the IRB's 28-member staff are trained to provide expedited reviews, and they also serve on the IRB.

They spend two days a week in the university's psychology building and at the biomedical campus, meeting with investigators who have questions or studies that might need expedited reviews, says Martha Jones, MA, CIP, executive director of the human research protection office. SWAT! received a 2012 Award of Excellence in Human Research Protection from the Health Improvement Institute.

"We wanted to be of service," Jones says. "We have expedited reviewers on staff, and they have authority to do approvals through the expedited review process."

Since opening the onsite office hours more than 18 months ago, the program has been well received. Every month, between 10 and 20 investigators visit each satellite office, she notes.

"We provide a more efficient way for studies to get approval through the expedited review process," Jones says.

The program also has a dedicated staff position for answering researchers' phone calls or responding quickly to online chat questions as they complete the protocol submission form electronically. These, as well as the staffed satellite offices, are available during weekday office hours, she adds.

SWAT! has grown to 300 to 450 monthly phone calls and its visits from biomedical researchers has increased by nearly 40% from a year ago, says Mike Leary, MA, CIP, education and compliance specialist in the human research protection office of WUSL.