2006 Conference: A Roadmap to Quality HRPPs

400 Attend Second Annual Event

The 2006 AAHRPP Conference: Quality Human Research Protection Programs drew nearly 400 representatives of hospitals, universities, government agencies, clinical research organizations, independent institutional review boards, and other groups concerned with ensuring the highest standards of human research protections. The increased attendance — up approximately 27% over last year’s successful event — is yet another indication of the growing recognition that accreditation plays a vital role in safeguarding research participants.

The 2006 conference was geared to individuals from both accredited and non-accredited organizations. It offered opportunities for attendees to interact with their peers, familiarize themselves with the accreditation process, and learn about innovative practices to improve protections for human research participants.

Plenary sessions covered a broad range of subjects, two of which — Ask Legal Counsel (below) and Regulations and Guidance: A Discussion with FDA and OHRP (page 5) — are featured in this edition of AAHRPP Advance. Conference materials and audio recordings of the plenary sessions are available on CD and may be purchased via the AAHRPP Web site at www.aahrpp.org. Simply click on the link for AAHRPP’s Annual Conferences and download the order form.

Ask Legal Counsel
Understanding and making the most of the IRB-counsel relationship

The question posed to legal counsel was a complicated one, prompted by a study comparing the results of different ventilator pressures on patients, most of whom suffered from some degree of decisional impairment. The institutional review board’s (IRB) concern was proxy consent — specifically, how the institution had ensured that consent had been given by the participant’s legally authorized representative under Pennsylvania law.

A preliminary review of the statute was not promising. Pennsylvania law is extremely restrictive, allowing a legal guardian to consent for research only if that power is specified in the guardianship order. Under the most rigid interpretation, then, proxy consent is virtually impossible. But what about individuals for whom guardianship has not been ordered by the courts? Who consents for them?

After careful consideration, a committee formed specifically to review the issue crafted a policy based on the principle of respect for person (autonomy). The policy presumes that research participants have the capacity to consent. In studies involving populations of questionable capacity, as part of the protocol, the investigator must describe how capacity will be assessed. Proxy consent is permitted when necessary, except in two instances: high-risk studies (for which additional review is required) and studies involving individuals whose guardianship has been determined

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Imagine a conference of nearly 400 people, brought together by a single common denominator: their commitment to the highest ethical practices for protecting research participants. Many of the 400 have already demonstrated this commitment by attaining AAHRPP accreditation. A great many more have yet to achieve accreditation but have set it as a goal. They are in attendance primarily to learn more about the accreditation process and what they must do to earn the designation that is now widely regarded as the gold standard for human research protection programs.

That was the case at AAHRPP’s second Annual Accreditation Conference, which was held in Phoenix earlier this year. Attendance was up by 27% — further proof that accreditation has, indeed, taken hold. In fact, in the 12 months since our first annual conference, we have marked milestone after milestone. The number of institutions attaining AAHRPP accreditation has nearly tripled, to 36 organizations with 103 entities. (See page 8 for Newly Accredited Organizations.) Another 370 institutions are in the midst of the accreditation process. Also since last year’s conference, leading professional organizations have joined us as Supporting Members (see News & Notes, page 8, for our two newest supporting members), and we were awarded a $4.9 million contract for the accreditation of the nation’s VA facilities.

These trends were reflected in our 2006 conference sessions. Presented by some of the most respected experts in human research protection, workshops and breakout sessions were designed to meet the needs of our increasingly diverse constituents. Separate conference “tracks” addressed accreditation issues specific to institutional officials and behavioral and social science research. Pre-conference workshops and plenary sessions tackled topics ranging from federal regulations and accrediting VA facilities to partnerships in the global research enterprise and the role of voluntary health agencies. Highlights from two sessions — Ask Legal Counsel (page 1) and Regulations and Guidance: A Discussion with FDA and OHRP (page 5) — are included in this issue. Conference materials and audio transcripts of five of the workshops may be purchased online at www.aahrpp.org. (Click on AAHRPP’s Annual Conferences and download the order form.)

As was the case last year, among the most appreciated aspects of the conference was the opportunity to network with organizations that are willing to share the benefit of their experience. We see that same spirit of collaboration in the HRPP Innovations (page 4) and Insights into IRBs (page 6), which are regular features in AAHRPP Advance. In this issue, Stanford University discusses its policy governing institutional conflict of interest, and the University of Texas at Austin describes a reorganization designed to enhance the service provided by its Office of Research Support and Compliance. Peter Vasilenko, Ph.D., IRB chair at Michigan State University, answers our questions about the importance of ongoing education for investigators, research staff, and IRB members and staff.

“In the 12 months since our first annual conference, we have marked milestone after milestone. The number of institutions attaining AAHRPP accreditation has nearly tripled…”

Looking ahead, please mark your calendar with the dates of our 2007 AAHRPP Conference, which will be held February 25-27 in Baltimore. We look forward to seeing you there. Meanwhile, if there are topics you’d like us to cover, feel free to send your suggestions to us at accredit@aahrpp.org.
Ask Legal Counsel
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by the courts. Furthermore, when proxy consent is required, the hierarchy for decision making is the same as that for clinical care.

In other words, consent that seemed impossible under the strictest legal interpretation was permissible under an IRB policy based on ethical considerations.

That example, presented as part of the 2006 AAHRPP Conference plenary session Ask Legal Counsel, is an excellent illustration of the role that legal counsel can play in assisting the IRB — and in supporting an institution’s commitment to human research protections. It also underscores the fundamental difference between the legal determination, which is the purview of counsel, and the ethical determination, which rests with the IRB.

The session was conducted by attorneys Theresa J. Colecchia and Patrick Taylor, who serve as legal counsel to IRBs at organizations with different, but equally effective, approaches to the counsel-IRB relationship.

Ms. Colecchia is Associate General Counsel at the University of Pittsburgh where she is assigned to a number of subject matter areas. She serves in an advisory capacity to the IRB, and as a non-voting member of an IRB committee responsible primarily for policy and compliance issues. The University of Pittsburgh has 11 IRBs.

Mr. Taylor is Deputy General Counsel and Chief Counsel, Research Affairs, at Children’s Hospital Boston. His role reflects Children’s Hospital’s historical commitment to human research protection and its need for an immediate response when legal issues arise. The hospital has one IRB.

Both Ms. Colecchia and Mr. Taylor emphasized that legal counsel’s role can vary but should not become domineering. For example, counsel can play a relatively narrow role, focusing primarily on ensuring that policies and activities are consistent with state and federal law. Alternatively, counsel can play a broader role, acting as a facilitator and helping the IRB secure organizational backing for major undertakings such as the decision to seek accreditation.

Both also agreed that, while it’s helpful to have legal counsel serve on the IRB, the role should be as a non-voting member.

“A lawyer’s advice must be credible, not reflecting a hidden agenda,” Mr. Taylor explained. “He or she must be very clear about what the laws are and must help in their application, but without dictating the results.”

Ms. Colecchia underscored a critical distinction between the role of legal counsel and that of the IRB. “I don’t feel it’s appropriate [for counsel] to vote on a particular protocol one way or another,” she said. “As long as the IRB is functioning properly, has the proper procedures in place, and is properly constituted, the determination of whether the protocol is within ethical standards and the law is a function of the IRB.”

Asking the right questions

Communication between the IRB and legal counsel is key and can often depend on how a question is phrased. When asked to interpret a regulation, Mr. Taylor said, counsel should first consider how others might interpret the law. Another response, however, is to view the request in the context of a particular organization and its approach to managing risk.

He suggested phrasing questions in this manner: “We feel very strongly about this issue. What’s the best way to structure this so that we can do it?” Follow-up discussions would touch on the following: “What are the risks of doing it this way for us as IRB members, for our organization, etc.?”

That was the approach taken in the proxy consent scenario, which was described previously. In that situation, Ms. Colecchia looked beyond the letter of the law to its intent. Additionally, the IRB convened representatives who provide medical care, advocacy, and caregiver services for individuals in varying states of incapacity to consider different perspectives on proxy consent. The IRB, with assistance from Ms. Colecchia, was then able to develop a policy that was both legal and ethical.

Advancing accreditation

Both Ms. Colecchia and Mr. Taylor stressed that the role of legal counsel depends on the culture of the organization and the extent of its commitment to its human research protection program. “One of AAHRPP’s enormous contributions is to help organizations, through a process of self-evaluation, come to an understanding of how central and supported your [the IRB’s] role must be,” Mr. Taylor said.

He urged IRB representatives to cultivate close relationships with legal counsel and to enlist counsel’s support in securing organizational backing for accreditation. “There are times when every IRB feels a little bit apart from the organization,” Mr. Taylor explained. “That’s why it’s important to make a very firm statement — and accreditation does this — about the fundamental importance of the human research protection program to everything that goes on in an organization.

“Accreditation results in genuine quality improvement and is one of the smartest things you can do,” he added. “Let counsel help you deliver this message throughout your organization.”

To purchase the complete audio recording of this plenary session, visit www.aahrpp.org, click on “AAHRPP’s Annual Conferences,” and download the order form.
A new conflict-of-interest policy at Stanford University — awarded full AAHRPP accreditation on March 17 — requires the institution to eliminate its financial stake in human research protocols either by divesting equity holdings that could be affected by the outcome of the research or by declining the research. Equally important, since faculty investigators often have no way of knowing about potential conflicts, the policy involves the university’s Office of Technology Licensing in reviewing protocols to identify and, therefore, avoid institutional conflicts. “The policy elevates the institutional commitment to eliminate conflict of interest, holding the university to the same high standard as that set for faculty and investigators,” explains Kathy McClelland, Stanford’s Research Compliance Director. “When an investigator has a potential conflict, the conflict of interest review program determines how it is resolved, often by divestiture of equity on the part of the conflicted investigator. This policy requires the institution to do the same.”

The goal of the policy is to preclude situations in which Stanford or Stanford investigators engage in research with human participants involving organizations in which the university holds ownership equity or rights to equity through licensing that is not publicly traded. In such situations, the university divests its holdings through the Office of Technology Licensing.

Since the policy was enacted in August 2005, there have been research proposals involving companies — usually smaller start-ups — in which Stanford has held the rights to the intellectual property. Whenever possible, Stanford has sold the equity back to the company. When, for financial reasons, a company has been unable or unwilling to repurchase the shares, Stanford has divested its interests by donating any resulting proceeds to charity.

According to Ms. McClelland, like other large academic research centers, Stanford has long grappled with the issue of institutional conflict of interest and has had procedures in place for many years. Last summer, the university took the additional step of codifying those procedures into policy in preparation for its accreditation application and site visit.

During policy discussions, officials realized that the scope of the university’s licensing activities made it extremely difficult for an investigator or IRB to determine the existence of an institutional conflict. “That’s when we decided to bring in the Office of Technology Licensing,” Ms. McClelland says. “As the one entity that knows if Stanford is receiving equity as partial consideration for licenses or royalties, it has a key role to play in the review process.”

Information: Kathy McClelland, kathy.mcclelland@stanford.edu, (650) 723-4697.

The University of Texas at Austin (UT) — awarded full AAHRPP accreditation on March 17 — has expanded and reorganized its Office of Research Support and Compliance, assigning new staff members to specific research disciplines to strengthen relationships with faculty and enhance their understanding of human research protections.

When the reorganization is complete, the Office of Research Support and Compliance will have four dedicated, professional IRB staff members. Each will be assigned, in accordance with his or her qualifications, to several of the following disciplines: pharmacy, sociology, psychology, kinesiology, biomedical engineering, nursing, social work, educational psychology, curriculum and instruction, advertising, marketing, government, chemistry, anthropology, communication sciences and disorders, human ecology, and special education, among others.

The changes will enable the office to better meet the needs of faculty, particularly those in the social and behavioral sciences, who often find it more difficult to apply human research protection regulations to their protocols. Under the reorganization, faculty will know precisely with whom to consult on specific questions. They also can be confident that their assigned staff member has both the appropriate credentials and the knowledge of the research protocol in question.

According to Lisa Leiden, Ph.D., C.I.P., Director, Office of Research Support and Compliance, the expansion and reorganization were prompted, in part, by UT’s preparation for its recent AAHRPP accreditation site visit. “As part of that process, we met with faculty to discuss our compliance efforts and ways that our office could serve them better,” Dr. Leiden explains.
Regulations and Guidance: A Discussion with FDA and OHRP

Regulations and guidance should work hand in hand, and the distinction between them should be readily apparent. Regulations spell out the requirements; they are the law. But the law also is open to interpretation, and, to assist with that interpretation, federal agencies issue “guidance.”

Under optimal circumstances, guidance clarifies the regulations and assists with decisions on compliance. In practice, however, guidance can complicate matters and even become burdensome.

The good news for those in the research enterprise is that the Food and Drug Administration (FDA) and the Office for Human Research Protections (OHRP) are aware of the concerns surrounding guidance, have made some changes, and are working on additional improvements. The not-so-good news is that additional change will take time. In some cases, confusion stems not from the guidance itself but from its application by those involved in conducting or overseeing research.

These were among the messages delivered by Bernard A. Schwetz, D.V.M., Ph.D., and Steven Gutman, M.D., featured speakers at the AAHRPP Conference plenary session "Regulations and Guidance: A Discussion with FDA and OHRP.

Dr. Schwetz is Director of OHRP. Dr. Gutman is Director of the FDA's Office of In Vitro Diagnostic Devices.

“When OHRP issues guidance, it’s not intended to be burdensome but to relieve burden,” Dr. Schwetz explained. Guidance is meant as a recommendation, he said, but often is misconstrued as a requirement.

Dr. Gutman concurred. “The regulations are binding and are cast in cement,” he said. “The guidances are exactly as Bern suggested — they indicate agency thinking. They put interesting and important scientific issues on the table. Those issues have to be addressed but not by following the letter of the guidance itself.”

Dr. Schwetz characterized guidance as falling on a continuum. On one end are suggestions about how to do things better; on the other are clarifications on the intent of specific regulations. Guidance on the first end of the continuum brings no new information to bear and doesn’t represent a new policy. It typically is issued in response to a question, burden, or uncertainty “telling you how to reduce the burden and still be compliant,” he said.

Guidance on the other end of the continuum focuses on interpreting a regulation. One example is the recent guidance on IRB review of clinical trial Web sites. “This is a relatively new issue and new guidance that’s much closer to an interpretation of the regulation,” Dr. Schwetz said.

Among the challenges faced by agencies that issue guidance is to balance conflicting requests from those in the research enterprise. Some organizations are more comfortable with guidance that offers specific instructions. Others consistently request more flexibility.

“The community is not of one voice,” Dr. Schwetz said. “Every time we ask what the community wants, in terms of guidance, there’s that tension between flexibility and direction — and you can’t have it both ways.”

Even so, agencies continue to solicit input on how to make guidance more readable and helpful. In fact, Drs. Gutman and Schwetz encouraged conference participants to voice their opinions when they disagree with guidance and its interpretation of a regulation. They urged attendees to take advantage of new tools, such as questions and answers that are now posted on agency Web site. And they spoke of additional enhancements — including joint FDA/OHRP guidance — in the future.

Reorganizing

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“Based on their feedback, we developed what we believe is a more customer-friendly approach, one that will make a significant difference for faculty while increasing institutional awareness of the research that we review.”

She views the new organizational structure as an opportunity to help faculty understand human research protection regulations, work with them to minimize the risks and increase the potential benefits of research protocols and, above all, safeguard research participants. She also envisions increased, mutual appreciation.

“When you’re involved in research, it’s what you live and breathe, and you want this office to feel similarly involved,” Dr. Leiden says. “You want your calls answered by someone who is familiar with your research and committed to helping you proceed in the right direction. You want customer service, which is exactly what these changes are designed to provide.”

Information: Lisa Leiden, Ph.D., C.I.P., Lisa.Leiden@mail.utexas.edu, (512)-471-8604.
Insights into IRBs

Keeping pace with the increasingly complex research enterprise is a challenge for even the most experienced investigators and institutional review board (IRB) members. Government regulations and institutional policies on research with human participants are subject to changing interpretations, and new technology often gives rise to new ethical dilemmas. In such a dynamic environment, a commitment to ongoing education is critical.

The responsibility for education and training rests primarily with human research protection programs. In the Questions and Answers below, Peter Vasilenko, Ph.D., discusses Michigan State University’s (MSU) comprehensive, innovative approach to fulfilling this responsibility. Director of the Human Research Protection Program at MSU and an IRB chair, Dr. Vasilenko also is a professor and researcher in the Department of Obstetrics and Gynecology at MSU’s College of Human Medicine.

Q. Why is education about human research protection so important?

A. The regulations are complex, and to digest them requires considerable thought and experience. Although they date back to the 1970s, we’re constantly getting new interpretations on enforcement through determination letters from the Office for Human Research Protections (OHRP). New ethical issues come up virtually every day, and technological advances present challenges that no one could have envisioned back when the regulations were drafted. We ask IRB members to review protocols in light of these changes, and we expect investigators to comply with them, but how can they know what the latest requirements are if we don’t keep them up to date?

There’s another side to this discussion as well. OHRP and the National Institutes of Health speak to general requirements about education and training but leave it to us to develop our own standards. At MSU, we’ve done that. Education is a big part of what we do, and it should be. Anyone who has contact with human research subjects in any way must complete our training program and fulfill our requirements for continuing education.

Q. In such a complex, changing environment, how do you keep IRB members and staff educated and up to date?

A. It takes multiple, ongoing efforts to keep people informed. Like most IRBs, we have an in-depth initial orientation during which we discuss the regulations and provide extensive background materials. We have mock applications and consent forms, deliberately designed with flaws for new members to detect. We also have new members serve as “shadow reviewers” for a number of protocols to give them a sense of the issues they will face. In addition, they participate in full board reviews at meetings. Then, we determine whether they’ve experienced enough to become reviewers using the expedited procedure for review. Although we have a full agenda for our IRB meetings, we always set aside 10 to 15 minutes for an educational issue. We subscribe to print and online publications, and we take advantage of e-mail to address issues as they emerge. We also have an annual retreat attended by members of all MSU IRBs, where we discuss issues that are more global in nature and require a standardized approach.

Our staff are professionals who are committed to staying abreast of a changing field. As a result, for staff education, we take a professional, comprehensive approach. In addition to our own extensive orientation and training, we take advantage of national meetings and conferences and encourage staff to become Certified IRB Managers and Certified IRB Professionals. Twice a month, we hold one-hour education meetings dedicated to current issues and emerging trends.
Q. How do you address the challenge of educating investigators and research staff?

A. We recognize that investigators have teaching and research responsibilities and have designed a comprehensive, flexible education program that, as much as possible, reflects their needs. We have our own tutorial covering the history of research at MSU and our specific policies and processes. When investigators apply for approval of a protocol, they must complete that tutorial. Investigators then have two years to complete a specified number of modules from the Collaborative Institutional Training Initiative (CITI) or our own supplemental modules. This gives investigators the flexibility to focus on those areas of greatest interest to them. We also offer a number of programs on campus that fulfill our education requirements, and we encourage attendance at our annual conferences for investigators, IRB members, and staff.

One of our objectives is to identify specific issues and find innovative ways to address them. Last December, for example, we scheduled a videoconference with representatives from OHRP to discuss the issues unique to education research. The videoconference lasted almost three hours and gave faculty and IRB members the opportunity to hear firsthand the parameters for research involving schools, students, and parents. It provided us with valuable insights into each other’s perspectives. We taped it, so we can now share it on DVD for others who are engaged in education research and wish to receive the training.

We view our relationship with investigators as a partnership. We can’t be there when they’re conducting research, so we have to rely on them to comply with the policies and regulations. They, in turn, have to rely on us to provide the proper training. It’s up to us to develop the right atmosphere and teach people to do the right thing — and at MSU, I think we’ve done that.

Q. Do you see any opportunities for collaboration?

A. I am very big on collaboration among IRBs. We host two conferences each year — a full-day multi-track session in the fall and a half-day session, devoted to a single issue, in the spring. These are open to investigators, IRB members, and staff and draw people from institutions from all over the state. Our Community Research IRB is composed of members of IRBs from across Michigan, with whom we partner in research. Each member has a home IRB, and we provide educational opportunities for all of them. In fact, one of the tracks at our annual fall conference is for new IRB members. If an IRB is adding a new member, the institution knows it can send the member to our conference for state-of-the-art training from experts in the field. Many IRBs across the state have come to rely on us for this training. Our conferences have become great forums for sharing ideas and debating issues. This collaboration of ideas has raised the level of all participants and IRBs involved.

Q. What about the future? Do you envision any additional programs?

A. We have a whole list of ideas, many of which build on our existing successes. Our retreat, for example, has drawn such a positive response that we’re considering holding discussion groups where IRB members could focus on policy and other issues apart from protocols. We’re working on applying MSU’s course management technology for IRB postings and to distribute IRB information electronically. We continue to develop CITI modules and, at the request of professors, to give presentations in specific classes. We also are creating a course on human research protections for which students would receive undergraduate or graduate credit. Ideally, I’d like to see this become part of every graduate student’s development, especially those who plan to conduct research.
More Supporting Members

Two organizations — the Amyotrophic Lateral Sclerosis Association and the Asthma and Allergy Foundation of America — have joined AAHRPP as Supporting Members. Our 10 Supporting Members represent a select group of professional, educational, and health-based organizations and businesses, all of which are committed to the highest ethical principles and standards in protecting research participants and the advancement of research.

New AAHRPP Director

We are pleased to welcome James A. Weyhenmeyer, Ph.D., to the AAHRPP Board of Directors as a public member. Dr. Weyhenmeyer is a professor of cell and developmental biology at the University of Illinois and has been involved with the American Heart Association for more than 25 years.

Council on Accreditation

The following individuals have been appointed to our Council on Accreditation:

**Gary Cseko, M.B.A., M.S.P.H.**
Director, Research Protections
The University of New Mexico Health Sciences Center

**Robin C. Ginn, M.B.A.**
Director, Research Informatics and Regulatory Affairs
Vanderbilt University

**John H. Mather, M.D.**
Vice President, Consulting and Research Services
Chesapeake Research Review, Inc.

**Joyce Miller, Ph.D.**
President
Keystone University Research Corporation

Important Dates:

- Accreditation Workshops
  - July 14, 2006
  - September 22, 2006
  - November 10, 2006

- Third Annual AAHRPP Conference
  - February 25–27, 2007
  - Baltimore, Maryland

Newly Accredited Organizations

The following organizations were awarded accreditation on March 17, 2006:

**Full Accreditation**

- Leland J. Stanford University, Stanford, California
- The University of Texas at Austin, Austin, Texas