

AAHRPP ADVANCE

WINTER 2009

Enhancing Protection for Research Participants

Maintaining Research Protections During an Economic Downturn

The economic crisis is having repercussions across the research enterprise. Declining endowments are taking a toll on private institutions, and government cutbacks threaten public programs. Falling stock prices and dwindling venture capital are placing pressure on pharmaceutical and biotech companies, while decisions to delay studies are slowing demand for the services of contract research organizations and independent institutional review boards (IRBs).

In this economic climate, many organizations face their most severe budget shortfalls in years. Many, even, are resorting to layoffs. The decision has become not whether to cut but how to do so wisely: how to preserve protections, improve efficiency, and continue to advance excellent, ethically sound research.

Protections Remain A Priority

The obligation to protect research participants is not contingent on economic conditions. In good times and bad, the research enterprise has a responsibility to preserve the systems and practices that safeguard participants and, in the process, can provide significant benefits to research organizations:

- **Furthering research.** High-quality human research protection programs (HRPPs) help ensure the integrity of the research process and of the data that are obtained.
- **Restoring public trust.** A commitment to research protections can help build trust and confidence and counter recent publicity about lapses in research ethics.
- **Solidifying gains.** The research enterprise has made significant progress in strengthening protections, improving compliance, and developing an infrastructure of support. Those gains will be lost if funding for protections is not deemed a priority.
- **Preparing for the future.** Changes in Washington, DC, have resulted in renewed respect—and the potential for additional funding—for science and research. If funds are approved, organizations with track records of compliance and accreditation will be best positioned to benefit.

Identifying Opportunities

An economic downturn can bring some unexpected benefits: the time and opportunity to make improvements that may be overdue. During

slower periods, HRPP staff re-examine policies and practices with an eye toward achieving greater efficiencies.

Organizations with multiple IRBs, for example, might find places to eliminate duplication. Those engaged in multi-site studies might realize savings and efficiencies by using an external IRB (see *New OHRP Director Outlines Priorities*, pages 4 and 5).

More difficult, but just as important, are the opportunities to develop innovative approaches to ensuring protections. Organizations that can innovate now may find themselves better prepared both to weather the current downturn and to capitalize on the brighter times to come.

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Association for the Accreditation of
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AAHRPP's View: Stand Firm on Ethics

One of the dangers of a declining economy is that we can be overcome by the problems of the moment. In the interest of short-term savings, we forgo long-term benefits. And when the recovery eventually comes, we cannot participate fully or immediately. Instead, we must rebuild the infrastructure that we sacrificed during leaner times.

At AAHRPP, we understand the difficult decisions that so many organizations face right now. But we also remind our colleagues across the research enterprise of the pitfalls of cutting back on compliance and losing ground on research protections (see *Maintaining Research Protections During an Economic Downturn*, page 1).

We have made significant gains as individual organizations and collectively. All told, 159 organizations representing more than 750 entities have demonstrated that they provide the protections required for accreditation (see *67 Earn Accreditation in 2008*, page 6). It would be an enormous mistake to erase these gains, especially since changes in the political climate give us reason to expect an increased emphasis on science and research in the coming years.

But what do we do in the meantime, while we wait for decisions on government investment and—in the more distant future—for the economy to rebound?

We start by acknowledging that now is not the time to de-emphasize research ethics and by continuing to advocate for stronger research protections. In keeping with our commitment to continuous improvement, we look for opportunities to work smarter. At AAHRPP, for example, we are seek-

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ing ways to simplify the accreditation process without lowering standards. We encourage human research protection programs (HRPPs) and institutional review boards to take advantage of the flexibility that's available in the federal regulations. We also offer assurances to those seeking accreditation that—although we certainly hold HRPPs to the highest standards—we don't expect any program to be perfect. When preparing for accreditation, focus on those items that will have the greatest impact on strengthening your human research protections.

One benefit of accreditation is that it creates an informal network of organizations willing to share their innovative practices. On page 3, we highlight the Cleveland Clinic, which is breaking new ground in its approach to conflict of interest, an issue that's received increased attention from Congress and the media. We applaud the Cleveland Clinic for its decision to publicize information on physicians' and researchers' industry relationships, and we urge others to consider similar acts of transparency.

Our Annual Conference (see page 7) provides the ideal opportunity to learn how others are responding to

the changing research environment. In one of this year's sessions, Thomas M. Priselac of Cedars Sinai Medical Center will discuss "The Role of Teaching Hospitals in Medical Research: Current and Future Challenges." Another session will feature Randolph Hall, Ph.D., of the University of Southern California, who will offer his views on "Helping Faculty Excel in Trying Times." A third session will introduce Jerry Menikoff, Ph.D., the new Director of the Office for Human Research Protections (OHRP). We provide a brief discussion of some of his priorities for OHRP on pages 4 and 5.

You can find more details on the conference, including registration information, at www.aahrpp.org.

Finally, we call your attention to the scientists who have been nominated to key positions in the Obama administration (see *Science and Research: 2009 Brings Cause for Optimism*, page 6). They are an impressive group, and we look forward to a renewed respect for science and research during their tenure.

— Marjorie A. Speers, Ph.D.

Online COI Disclosure at Cleveland Clinic

Cleveland Clinic has taken the lead in disclosing physicians' and researchers' ties to industry by publicizing that information online, making it easily accessible to patients and research participants.

The online disclosure began last fall as part of Cleveland Clinic's comprehensive program to manage and minimize financial conflicts of interest (COI). Cleveland Clinic is believed to be the first major U.S. medical center to provide this information, which is included in each physician's online biographical sketch.

"We believe that patients and research participants want this information," says Guy M. Chisolm III, Ph.D., who spearheaded the disclosure effort. The Vice Chairman of the Lerner Research Institute of Cleveland Clinic and Director of Cleveland Clinic's Innovation Management and Conflict of Interest Program, Dr. Chisolm expects interest in COI and industry relationships to continue to grow in response to increased media and government scrutiny.

The Cleveland Clinic Web site features disclosures in five categories: consulting arrangements resulting in payments of \$5,000 or more per year, royalty payments, equity obtained as founder or inventor, inventor shares, and fiduciary roles. The online material is culled from information that Cleveland Clinic requires its physicians and researchers to report each year.

According to Dr. Chisolm, one of the challenges was to identify information that would matter most to patients and research participants—and to present that information in a

meaningful way. As an example, he points to the decision to look beyond royalty payments to royalty rights as well.

"You have a potential for conflict as soon as you have a right to royalty, even if you haven't received a penny," Dr. Chisolm explains.

Cleveland Clinic has about 2,000 physicians and researchers worldwide. Of those, approximately one-quarter have industry relationships that must be disclosed. Patients can access those disclosures at www.clevelandclinic.org, under "Find a Doctor," by typing in a physician's name and clicking on "Industry Relationships."

If the physician/researcher has nothing to disclose, that is noted. When industry relationships do exist, company names are listed under the appropriate category. Although dollar amounts are not included, they could be added in the future, provided

CONTINUED ON PAGE 5

Progress Report: Financial COI

Research organizations face continued pressure to strengthen policies on financial conflict of interest (COI) and to step up enforcement. Following is a brief update on COI efforts:

- National Institutes of Health (NIH): NIH may make changes to its regulations for financial COI within the next 12 months. NIH has submitted an advance notification of proposed rule making (ANPRM) to the Office of Management and Budget and expects the ANPRM to be published during the first quarter. Public comment will be solicited for 60 days and will address questions about strengthening NIH oversight and management, expanding disclosure requirements, and confirming institutional compliance.
- Academic medical centers: Cleveland Clinic lists industry relationships online as part of its physicians' and researchers' biographical information (see *Online COI Disclosure at Cleveland Clinic*, this page). The University of Pennsylvania School of Medicine plans to make similar information available later this year via a searchable Web site. The University of Minnesota Medical School is considering what would be one of the toughest conflict of interest policies in the nation.
- Pharmaceutical companies: GlaxoSmithKline (GSK), Eli Lilly and Company, and Merck & Co. have said they will disclose payments to physicians for speeches and consulting, starting later this year. Other pharmaceutical firms have joined Eli Lilly, Merck, and GSK in endorsing the Physician Payments Sunshine Act, which is sponsored by U.S. Senators Chuck Grassley (R-IA) and Herb Kohl (D-WI).

New OHRP Director Outlines Priorities

Jerry Menikoff, M.D., J.D., joined the Office for Human Research Protections (OHRP) in October as Director. Previously he served as Director of the Office of Human Subjects Research and as a bioethicist, both at the National Institutes of Health. Dr. Menikoff holds a medical degree from Washington University in St. Louis and degrees in law and public policy from Harvard University. He has written extensively on research ethics and the protection of research participants.



Below, Dr. Menikoff describes some of his goals for OHRP: helping research organizations make better use of scarce resources; providing additional, more useful guidance; improving communication; and addressing issues surrounding informed consent.

Helping Organizations Maximize Resources

Limited resources are a fact of life in the world of institutional review boards (IRBs), and that certainly isn't going to change any time soon. In the current economic environment, it's critical that we help organizations use their resources more effectively.

One way to reduce duplication of effort could be to encourage more reliance on external IRBs, especially for multi-site studies. What is the benefit—to the research and to the subjects—of having multiple IRBs review the same information? If we eliminate this duplication, perhaps we could devote some of these valuable resources to activities that improve research protections.

It's also important for human research protection programs (HRPPs) and IRBs to prioritize their efforts. Research studies span the continuum from very low risk to high risk, and the system is designed to allow HRPPs and IRBs to focus different amounts of attention on different types of studies. We could spend hours reviewing a low-risk study, but that creates an inappropriate burden for researchers and IRBs and does little to improve protections. It's far better to devote that time to riskier studies—to providing the review and protections that make such studies possible. We're not suggesting that protections be weakened; we're talking about giving HRPPs and IRBs greater ability to expend their resources to strengthen protections for riskier studies.

Harmonization is another example. A few weeks ago, FDA issued guidance on retaining information on subjects who are no longer involved in a research study (see *News & Notes*, page 8), and OHRP released draft guidance on the same topic. The wording is a little different, but the underlying theme is the same. When a researcher has collected information that's designed to answer a research question, that information should not be stripped out of the study simply because, for one reason or another, the research subject is no longer participating. The guidance from FDA and OHRP is very similar, and that makes it easier for everyone concerned. Any time you have two agencies with two sets of rules that are intended to accomplish the same goal, differences in the application of those rules can make it more difficult for people to abide by the rules while at the same time failing to produce superior results.

Offering Effective Guidance

We often hear that it's better not to provide specific guidance—that the absence of guidance allows people

The goal is not just to provide more guidance, but to do so in a way that makes our system function better—to provide guidance that protects subjects while highlighting the flexibility that's available to researchers.

greater flexibility in interpreting the regulations. In my experience, the opposite can be true. Guidance can empower individuals and advance both research and research protections.

In the absence of guidance, people tend to be reluctant to take certain actions out of fear that they are violating the rules. In some instances, important research is not even attempted, all because of a misunderstanding. Guidance could eliminate the misconception and clear the way for research.

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Encouraging Honest Communication

We'd like to improve the lines of communication, in both directions, between OHRP and the communities it serves. A good place to start is to let people know we're actively seeking their input. We also have to make it easier for them to contact us, and we have to assure them that their privacy will be protected.

We live in a world where it's very easy to communicate electronically, and it makes sense to take advantage of that. We're exploring ways to increase OHRP participation in online discussion communities. We're also looking at redesigning our Web site to make it more user-friendly. We want people to be able to find what they're looking for as quickly as possible. We also want to offer opportunities for them to comment anonymously—to eliminate any concerns they may have about communicating with a government agency and, as a result, allow them to be honest with us.

Underscoring the Importance of Obtaining Informed Consent

Obtaining voluntary informed consent is critical to the legitimacy and integrity of research, and it's one area in which I would hope we'll provide more guidance. When people are putting their health—and, possibly, their lives—on the line to participate in a research study, it's up to us to ensure that they're making an enlightened decision. Our society generally chooses not to use people against their will. Instead, we let them decide whether they want to participate in generating new knowledge, and we give them the information they need to weigh the risks against the potential benefits.

One of the roles of the informed consent process is to address some of the underlying conflicts that are built into our system. We have a system that allows pharmaceutical companies to design and conduct research

studies that have the potential to provide important benefits. It's certainly not our goal to discourage or prevent these studies. But it is up to the investigator and sponsor, with the IRB's approval, to disclose the involvement of the pharmaceutical company during the informed consent process. The scope of that disclosure could include making sure the research subject is aware when an investigator is being compensated by a pharmaceutical company and what form that compensation takes.

Informed consent is at the core of the responsibility that we assign to IRBs, and there are a number of questions that need to be answered. What, for example, should research subjects be told about the financial conflict of interest of a physician investigator who is asking them to enroll in a research study? This is something that is well worth addressing further.

Cleveland Clinic CONTINUED FROM PAGE 3

government regulators, pharmaceutical and medical device companies, and research institutions agree on a standard format for reporting.

"Our goal is to provide information that helps the public," Dr. Chisolm says. "We don't want to undermine that with discrepancies in reporting."

Reaction to the current online disclosure system has been positive, both within and outside Cleveland Clinic. Even so, Dr. Chisolm wants to make certain that Cleveland Clinic is presenting the information that best serves patients and research participants.

In the coming weeks, Dr. Chisolm, in collaboration with the Office of Patient Experience, will survey 2,000 patients, asking pointed questions about the type of information they'd like to see. Input will also be sought during patient focus groups.

"Our plan is to design these pages the way that patients want, with the information they care about," Dr. Chisolm says. "We still have work to do, but we are well on our way."

Information: Guy M. Chisolm III, Ph.D., CHISOLG@ccf.org, (216) 444-5854

Science and Research: 2009 Brings Cause for Optimism

Despite the bleak economic news, some scientists and researchers are more optimistic than in recent years—largely because of key picks announced by the Obama administration.

- **Steven Chu, Ph.D.**, a Nobel laureate in physics and Director of the Lawrence Berkeley National Laboratory, as Secretary of Energy.
- **John P. Holdren, Ph.D.**, a Harvard physicist, as Director of the White House Office of Science and Technology Policy, the president's science adviser. Dr. Holdren also will be one of three Co-Chairs of the president's Council of Advisers on Science and Technology.
- **Harold E. Varmus, M.D.**, Nobel laureate in physiology or medicine and winner of the National Medal of Science; and **Eric S. Lander, Ph.D.**, a leader of the Human Genome Project; as Co-Chairs of the Council of Advisers on Science and Technology.
- **Jane Lubchenco, Ph.D.**, a marine biologist at Oregon State University, to lead the National Oceanic and Atmospheric Administration.

Two of these choices, Dr. Holdren and Dr. Lubchenco, have served as Chair of the American Association for the Advancement of Science.

67 Earn Accreditation in 2008

AAHRPP accredited 67 organizations in 2008, an increase of 42.6 percent over the previous year—and the most accreditations in any single year since AAHRPP was founded.

To date, 159 organizations representing more than 750 entities have earned accreditation. Among them are the following organizations, which were awarded accreditation in December:



Full Accreditation

- **Aspire Independent Review Board, LLC**, La Mesa, CA
- **Bay Pines VA Healthcare System**, Bay Pines, FL
- **Coatesville Veterans Affairs Medical Center**, Coatesville, PA
- **Hampton VA Medical Center**, Hampton, VA
- **IRC – Independent Review Consulting, Inc.**, Corte Madera, CA
- **Jesse Brown Veterans Affairs Medical Center**, Chicago, IL
- **Miami VA Healthcare System**, Miami, FL
- **Michael E. DeBakey VA Medical Center**, Houston, TX
- **Roswell Park Cancer Institute**, Buffalo, NY
- **Salem VA Medical Center**, Salem, VA
- **St. Louis VA Medical Center**, St. Louis, MO
- **University of Wisconsin-Madison**, Madison, WI
- **VA Greater Los Angeles Healthcare System**, Los Angeles, CA
- **Veterans Affairs Maryland Health Care System**, Baltimore, MD
- **Washington DC VA Medical Center**, Washington, DC
- **Wilkes-Barre VA Medical Center**, Wilkes-Barre, PA
- **William Jennings Bryan Dorn Veterans Affairs Medical Center**, Columbia, SC
- **William S. Middleton Memorial Veterans Hospital**, Madison, WI
- **Winthrop University Hospital**, Mineola, NY



Qualified Accreditation

- **Durham VA Medical Center**, Durham, NC
- **VA Tennessee Valley Healthcare System**, Nashville, TN

2009 AAHRPP Conference

Quality Human Research Protection Programs

Registration is underway for the 2009 AAHRPP Conference, which will be held February 22-24 in Los Angeles. Topics include:

Quality Improvement

- Components of Model Quality Improvement Programs for Human Research Protection Programs
- Quality Improvement of IRBs: Methods and Metrics
- Quality Improvement Activities Targeting Investigators and Research Staff: Audit and Satisfaction Surveys
- Quality Improvement Programs: Conducting Audits of IRB Records, Minutes, and Consent Documents
- Quality Improvement Programs: Post-Approval Monitoring of Research Studies
- Quality Improvement Activities Targeting Research Participants

Benefits of Accreditation

- Value of Accreditation I: Exerting Flexibility
- Value of Accreditation II: The Role of Senior Leadership
- Value of Accreditation III: Attracting Sponsors
- Value of Accreditation IV: Findings from FDA and OHRP Inspections

For VA Facilities

- Role and Function of Research Compliance Officers in VA Facilities
- Update on VHA Handbook 1200.5
- Privacy and Data Management Within the VA
- Reaccreditation Procedures for VA Facilities
- Reporting Requirements Within the VA

International Research

- Seeking Consent in Asian Countries
- Recent Developments in Clinical Trials in Korea

Research Trends and Challenges

- The Role of Accreditation in an Ever-Changing Research Enterprise
- Conflict of Interest – Views from Washington
- The Organizational Official's Headache – Tensions Between IRBs and Researchers
- Helping Faculty Excel in Trying Times
- Strengthening Public Trust: Sponsors and Accreditation

More information, registration:
www.aahrpp.org

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NEWS & NOTES

Guidance Updates

- **On records retention:** Researchers must retain private information for clinical trial participants even after the participants have withdrawn from the research study, according to final FDA guidance issued December 1 (<http://edocket.access.gpo.gov/2008/E8-28387.htm>). The guidance is designed to ensure that information obtained during a study is not removed from the database. The Office for Human Research Protections (OHRP) has issued similar draft guidance.
- **On multi-site IRB review:** Under new OHRP guidance for cooperative research (www.hhs.gov/ohrp/humansubjects/guidance/engage08.html), an organization must ensure that its institutional review board (IRB) reviews and approves the parts

of the research in which the organization is engaged. The guidance also permits the following for cooperative research projects: joint review, reliance on review by another qualified IRB, or other arrangements that avoid duplication of effort.

Director of Marketing and Communications

David Ward has joined AAHRPP as Director of Marketing and Communications. Mr. Ward has extensive experience in marketing for non-profit and commercial organizations. Most recently, he consulted with the Association of Family Farms to help it encourage and certify regionally sustainable food value chains. Previously, he served as Vice President for Marketing, Business, and Program Development at the Rodale Institute and Vice President of Marketing at World Wildlife Fund.

ACRP Acting President & CEO

James Thomasell, C.P.A., has been named Acting President and Chief Executive Officer of the Association of Clinical Research Professionals (ACRP). Mr. Thomasell has more than 18 years of experience in financial and operational management, including three years as ACRP Director of Finance and Administration.

International Compilation of Human Subject Protections

The 2009 edition of the International Compilation of Human Subject Protections is available at www.hhs.gov/ohrp/international/HSPCompilation.pdf. The compilation lists approximately 1,100 laws, regulations, and guidelines for human subjects research in 92 countries, as well as standards from a number of international and regional organizations.