PROTECTING HUMAN SUBJECTS

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DOE's policy is a graded approach

DOE-accepted plans for self-assessment and external review

by Elizabeth White, DOE Human Subjects Protection Program Manager

Elizabeth White

More than a decade ago, the DOE's Human Subjects Protection Manager (Susan Rose) instituted a rigorous system of regular external reviews of the human subjects protection programs at our DOE sites.

This was an important step toward ensuring a high level of commitment to human subjects protection within DOE, and the Department continues to place significant emphasis on regular self-assessment followed by some form of external review.

Our goal is not only to ensure that our research laboratories and other facilities across the country meet federal and Department requirements, but also to encourage and assist our DOE sites with becoming leaders in the field of human research subject protection.

Workshop for DOE sites

Last spring our office hosted a workshop for our DOE sites as a step toward renewing the Department's commitment to quality improvement and learning more about tools available to the human subjects protection community. These include the Association for the Accreditation of Human Research Protection Programs (AAHRPP) self-assessment

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A flexible alternative

OHRP's Quality Improvement Program was a better fit for Sandia National Laboratories' smaller IRB

by Terry Reser, Administrator, Human Studies Board, Sandia National Laboratories

Terry Reser

It's good to know where you stand.

Most of us affiliated with an IRB know this line of work is a career, not just a job. We also like to know that we measure up—that our program for protecting human subjects stacks up against any other, anywhere, anytime.

But what's the right gauge to measure this?

Until recently, the only gauge getting any press was accreditation through the Association for the Accreditation of Human Research Protection Programs (AAHRPP). AAHRPP has a great program and is an excellent tool for vetting a human research protection program at large institutions like universities, hospitals, and other research facilities that conduct hundreds of protocols a year.

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What we learned

PNNL's experience with the accreditation process

by Sherry Davis, Pacific Northwest National Laboratory

Sherry Davis

Being the first of the Department of Energy (DOE) national labs to complete the accreditation process, Pacific Northwest National Laboratory's Human Research Protection Program (HRPP) found itself playing the guinea pig role—ironic, given the job we do.

It is time consuming and difficult, but worth it in the end. For example, applicants must demonstrate

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In this issue

This edition of *Protecting Human Subjects* focuses on issues of self-assessment, external review, and accreditation as ways to improve IRB effectiveness.

Included are articles about DOE national laboratories that decided to pursue accreditation and others that are using other forms of self-assessment and external review.

Also included are supporting voices for accreditation and dissenting voices arguing that accreditation will create a more unwieldy review system, especially for human subjects research in the humanities and social sciences, and do little to enhance human protections.

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DOE's policy is a graded approach

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instrument and accreditation process (http://www.aahrpp/org), as well as the combined use of the Office of Human Research Protections (OHRP) self-assessment instrument and voluntary submission to a comprehensive review by members of the OHRP Education Division (http://www.hhs.gov/ohrp/qi).

We are in the process of working with our sites to develop site-specific plans and timelines for regular (every 3-5 years) self-assessments and external reviews.

Pacific Northwest National Laboratory achieved accreditation through AAHRPP this year, and Brookhaven National Laboratory is undergoing this accreditation process in conjunction with the State University of New York at Stony Brook. DOE encourages those sites that engage in "more-than-minimal-risk" human subjects research to seek accreditation. Other sites may use the OHRP two-step quality assurance program described above. Sandia National Laboratories and Oak Ridge have already completed the OHRP review process and found it to be very rigorous and extremely helpful.

Still another option for DOE sites that do not make use of either of these external review programs is to initiate their own external reviews and/or to undergo Headquarters-initiated external reviews.Δ

OHRP: New guidance on human subjects research

OHRP has posted on its website a "Guidance on Engagement of Institutions in Human Subjects Research" (http://www.hhs.gov/ohrp/humansubjects/guidance/engage08.html). This new guidance document replaces two prior OHRP guidance documents on the engagement of institutions in human subjects research: (1) the January 26, 1999, document on "Engagement of Institutions in Research," and (2) the December 23, 1999, document on "Engagement of Pharmaceutical Companies in HHS Supported Research."

OHRP has also posted a revised version of the "Guidance on Research Involving Coded Private Information or Biological Specimens" that includes minor changes: http://www.hhs.gov/ohrp/humansubjects/guidance/cdebiol.htm.Δ

News notes

Study finds IRB policy gaps

Most IRBs explicitly prohibit a conflicted member from participating in discussion and voting, but few explicitly prohibit serving as a reviewer or extend their policies to cover IRB staff, according to an article in The Hastings Center's *IRB: Ethics & Human Research* (http://www.thehastingscenter.org/Issues/Default.aspx?v=1416).

The article, "Conflicts of Interest in Research: How IRBs Address Their Own Conflicts," is written by **Leslie Wolf** and **Jolanta Zandecki**.

They conducted the study to determine whether institutions address conflicts of interest among their IRB members and staff, and, if so, in what ways. They analyzed policies for 121 U.S. medical schools. About three-quarters of the schools studied have written policies that address IRB conflicts of interest, and almost 80% of them defined the term, although their definitions varied substantially. The findings illustrate important gaps in these policies, the authors say. A few policies even conflict with federal requirements.

Fields named manager of Former Worker Medical Screening Program

Mary Fields has been named Program Manager for the DOE Former Worker Medical Screening Program (FWP) in the Office of Health, Safety and Security (HSS), Office of Former Worker Screening Programs.

During her previous nine years in HSS and its predecessor organization, the Office of Environment, Safety and Health, Fields provided contractor support to such programs as the FWP and the DOE Beryllium Bio-Repository initiative. In these positions, she worked closely with the Office of Science and applicable IRBs to ensure initial and ongoing compliance with human subjects protection requirements.

Fields is currently working with **Elizabeth White**, the DOE Human Subjects Protection Officer, to jointly develop a streamlined IRB review process for FWP informational and informed consent materials.Δ

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PNNL: What we learned in accreditation

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compliance with 27 standards and 77 elements in five domains: organization, investigators, sponsored research, participant outreach, and the research review unit or institutional review board. Satisfying this requires an in-depth review of every policy, procedure, and form in the HRPP.

The following are some things we learned along the way as we worked with the Association for the Accreditation of Human Research Protection Programs (AAHRPP):

- Keep it simple. Write it once and refer often. For instance, rather than repeat the reporting process for each element, refer to a "Reporting" section in the web site.
- If it's not written down, it's not a policy or procedure.
- Don't paraphrase. Cite the regulations verbatim.
- Provide accurate definitions.
- Clearly state each step in the process. Describe why the policy and procedure is required, what is required, when is it required, who is responsible for what, where and how is the act accomplished, and how the final outcome is reported and documented to ensure compliance.
- If any part is missing, the element, standard, and, ultimately, the requirements of the Domain will not be met. This is the strength and the difficulty in using AAHRPP's self assessment guide.
- Constant communication with AAHRPP is critical to ensure that their terms and expectations are understood.

We did encounter problems, and there are drawbacks, including that it is a long and arduous process, particularly when the responsibility falls to one person, usually the IRB administrator. While regulatory compliance is the same, human research at DOE laboratories is very different than that conducted at universities and clinics, which AAHRPP accreditation is geared to. Terminology and requirements can be unfamiliar and/or not implemented at DOE.

Central to the process was a 2-day site visit by AAHRPP, which involved in-depth interviews with institutional officials, legal and contracts staff, researchers, and IRB members, including the chair, vice chair, and program manager. The visit also involved lengthy review of project and IRB files. All of this required significant training to prepare for the visit.

Among the differences between accreditation and OHRP's assessment is that four different filings were required. The first was a preliminary application. The second was a formal application used by the site visitors to assess compliance and to write the site visit report. The third was our response to the site visit report, which was submitted to the Council on Accreditation. The fourth was our response to the Council on Accreditation's comments. So, getting accredited isn't easy, but there are many benefits:

PNNL's efforts toward obtaining accreditation greatly improved our program. The self-assessment was an especially invaluable tool. The process increased our overall knowledge and depth of understanding for topics we had little experience with. It also resulted in a greater awareness by laboratory and institutional management and, best of all, a fully accredited HRPP. We now are able to:

- Demonstrate to sponsors that our organization values research protections, follows regulatory requirements, and has an efficient, streamlined human research protection system.
- Demonstrate to potential human subjects that our organization is committed to protecting the rights and welfare of subjects.
- Attract high-quality investigators who can have confidence in the IRB and in an organization that supports human subject research.
- Increase our efficiency and reduce costs by streamlining operations and eliminating duplicative efforts.
- Foster alliance with other accredited and like-minded organizations.

We began the process with AAHRPP's self-assessment tool, which is the most important and most time-consuming part of accreditation. The HRPP web site provides all other required guidance, policies, and procedures for the HRPP. Every aspect of this was examined in the self-assessment process, beginning with a gap-analysis against the 77 elements. This told us where the program was in compliance and where revisions, changes, or entirely new information were required.

This resulted in totally reformatting, revising, and updating the HRPP web and SBMS sites, both of which had been developed in the late 1990's, to comply with new PNNL formatting standards and AAHRPP requirements.Δ

The review is very thorough, but also quite collegial; they want to catch you doing things right. When I spoke to folks here afterward, all who were interviewed felt that their time was well spent, and they came away with a much better understanding and appreciation of the "feds."

A flexible alternative to accreditation?

(Continued from page 1)

But for smaller shops, the accreditation process doesn't allow the IRB to achieve an economy of scale as it does for a large facility, so it becomes expensive, time-consuming, and, well, draining —according to several folks who have gone through it.

Luckily, the Office for Human Research Protection (OHRP) now offers an alternative. OHRP's Quality Improvement Program (QIP) functions much the same—a vetted program for evaluating an HRPP—but it's a better fit for small IRBs. It makes more reasonable demands on your time, is more flexible, and it's free!

You can't go back

Also, once you start with accreditation, you can't go back; you have to get reaccredited every 3 years. There's a definite stigma attached to having been accredited and losing that accreditation for whatever reason. With the QIP, there is no time expiration on the evaluation, so this issue disappears.

"The whole process from beginning the SA to concluding the site visit was about three months. Not too bad, considering. We received verbal feedback at the closeout briefing, and received written followup about two months later."

Sandia recently volunteered to be the first DOE site to go through OHRP's Quality Improvement Program. Here's how it went.

Self-assessment

The QIP consists of a self-assessment (SA) tool and a follow-up consultation with OHRP. The SA is available on the OHRP website (http://www.hhs.gov/ohrp/qi/), so you can access it anytime. It consists of 98 questions to help you determine specifically where the strengths are in your program and what might need some work.

Once you finish it and are ready for some scrutiny, contact OHRP and they'll send you a list of what information they need to review before they conduct the consultation. This includes your written procedures, minutes from several IRB meetings, and records that show how exempt, expedited, and full board reviews were processed. Any other relevant documentation can also be sent. Plan on getting this information to OHRP at least six weeks before the consultation.

The consultation itself may be onsite or via phone, depending mostly on OHRP's workload. If onsite, count on a day and a half, and they'll want to talk with IRB members, researchers, and the institutional official, as well as with the Administrator and Chair. We arranged the visit at SNL to coincide with our regular IRB meeting, which simplified the logistics considerably.

Time well spent

The review is very thorough, but also quite collegial; they want to catch you doing things right. When I spoke to folks here afterward, all who were interviewed (IO, IRB members, and researchers) felt that their time was well spent, and they came away with a much better understanding and appreciation of the "feds" we deal with.

The OHRP folks, in turn, said that they had visited several other IRBs already and thought they knew what to expect here, but they learned that DOE sites are quite different from the IRBs they've consulted so far. (Their next epiphany will likely be when they figure out how unique we each are within the DOE complex.)

The whole process from beginning the SA to concluding the site visit was about 3 months. Not too bad, considering. We received verbal feedback at the close-out briefing and received written followup about two months later.

All in all, for our site this gauge seemed to be sized just right. It was useful, positive, and most of the time it felt, well, comfortable.Δ

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For Oak Ridge, one size does not fit all

OHRP's Quality Improvement Program was perfect fit for Oak Ridge's unique situation

by Becky Hawkins & Betsy Ellis, Oak Ridge Institute for Science & Education, - & Leigh Greeley, Oak Ridge National Laboratory -


Becky Hawkins


Betsy Ellis


Leigh Greeley

Terry Reser is right.

Just as "one size does not fit all," and just as all human subjects projects do not require the same level of review, neither do all human subjects protection programs. (*See article by Terry Reser of Sandia National Laboratories beginning on page 1.*)

OHRP's Quality Improvement Program (QIP) was a perfect fit for us at Oak Ridge. Terry's volunteering to go first was helpful, giving us a heads-up about what to expect.

Additional challenge

The review of our program presented OHRP with an additional challenge, because we have a unique program. Our biggest hurdle in preparing for our review was getting all the players together, which sometimes felt like trying to herd cats.

We had two institutions (Oak Ridge Institute for Science & Education and Oak Ridge National Laboratory), two IRBs (Oak Ridge Site IRB and the Central Beryllium IRB), two Institutional Officials, two Human Studies Coordinators, two IRB Chairs, PIs and Board members from two institutions, and, yes, one IRB administrator.

The rest of the process was just as Terry explains it. It was intense, and it was thorough.

Our web-based electronic management system allowed us to give access to the reviewers and share with them the documents they asked to see. We were able to address many of their questions and clear up issues prior to their visit.

Our already strong relationship with DOE was strengthened by having **Elizabeth White**, DOE Human Subjects Protection Program Manager, and **Peter Kirchner**, MD, the Program's Senior Medical Scientist, involved with us in this review process.

Getting things done right

We came away knowing that our human subjects protection program was pretty gosh darn good, and we welcomed the suggestions and recommendations provided by the reviewers. We do not want to just get things done, we want to get things done right.

Our letter from OHRP indicating that we successfully completed the process arrived within two weeks. It sure is nice to have our efforts validated at that level of expert review.

The fact that OHRP is willing to do these on-site reviews (yes, free) is a testament to their commitment to ensure that our institutions understand the regulations and that human subjects protection in research is something that they and we take very seriously.Δ

News notes

New research ethics blog

A new blog on research ethics is at: **http://www.researchethics.ca/blog/**

The blog is authored by **Nancy Walton** with the help of **Chris MacDonald**, authors of the "Business Ethics Blog."

Walton is Research Ethics Board Chair at Ryerson University in Toronto. Topics on the new blog include the commercial influence on research and publishing.

New OHRP director named

Jerry A. Menikoff has been named director of the Office for Human Research Protections (OHRP), part of the Office of Public Health and Science, in the Office of the Secretary.

Prior to joining OHRP, Dr. Menikoff served as the director of the Office of Human Subjects Research and as a bioethicist, both at the National Institutes of Health. He has written extensively on research and human subject protections.

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Environment of concern led to accreditation

Suspension of research programs in large, respected academic medical centers was part of the impetus for establishing rigorous standards and continuing diligence.

Accreditation in human research protection is a relatively new concept. Born in the early 2000's as a response to increased governmental scrutiny of human research protection programs, accreditation has become the hallmark of high-quality human research protection programs.

Marjorie Speers

As the "gold seal," the Association for the Accreditation of Human Research Protection Programs (AAHRPP) accreditation offers assurances—to research participants, researchers, sponsors, government regulators, and the general public—that a human research protection program is focused first and foremost on excellence.

by Marjorie Speers, AAHRPP President and CEO

AAHRPP is a non-profit organization offering accreditation to organizations that conduct or review research involving humans. This vast research community includes government agencies, hospitals, universities, research institutes, independent IRBs, contract research organizations, and even pharmaceutical and biotechnology companies.

In 2003, the Department of Energy was the first federal agency to ask for AAHRPP accreditation for its research programs in its national laboratories.

Focus is more than the IRB

Accreditation was founded on the premises that well-founded research ethics are an integral component of a sound and quality driven research policy and that the focus of responsibility for protection of human subjects must be expanded to include investigators and organizations. The focus cannot be solely on the IRB.

For this reason, the locus of accreditation is the "human research protection program"; which encompasses all the policies, procedures, and activities.

Accreditation recognizes the roles and responsibilities of IRBs that have the primary responsibility of ensuring that research studies are ethically justifiable and that protections are in place to make the research study as safe as it can be, given the inherent risks associated with any clinical study.

Accreditation also recognizes the roles and responsibilities of investigators and research staff who conduct research studies. These individuals often design the research study, administer the consent process, obtain consent, carry out the procedures and interventions, analyze the data, report findings to subjects when appropriate, and do all the other things that researchers do. Their obligation to protect research subjects is just as strong as that of the institutional review board.

Shared responsibility

IRBs and investigators cannot perform their duties without the support of their organizations. Thus, the focus of accreditation on a program of human research protection brings together all these roles and responsibilities and acknowledges that protection is a shared responsibility in which the system is only as good as the weakest link.

AAHRPP's accreditation model has three distinct characteristics. First, it is a voluntary and non-governmental process. Organizations seek accreditation because they place a high priority on protection. By being nongovernmental, standards are set higher than the floor set by federal agencies and are able to address known weaknesses in the regulations.

Peer-driven

Second, it is peer-driven. Standards and procedures were agreed upon by those who would be affected: ethicists, IRB professionals, researchers, and research subjects. When site visitors are respected colleagues, organizations listen.

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New books

The Body Hunters: Testing New Drugs on the World's Poorest Patients, by Sonia Shah (The New Press, $24.95)

An investigative journalist's overview of the pharmaceutical industry's practice of conducting human research in developing countries. A review by Jennifer Bard appears in *The American Journal of Bioethics*, Vol. 8, No. 2, February 2008.

Brookhaven lab seeking accreditation

by Darcy Mallon, Administrator, Institutional Review Board, Brookhaven National Laboratory


Darcy Mallon

The Humans Subjects Research Program (HSRP) at Brookhaven National Laboratory (BNL) has begun the process of accreditation by AAHRPP.

DOE has always requested sites involved in human subjects research ensure that their HSRP is compliant with all local, state, and federal regulations governing human subjects research. This can be accomplished in a variety of ways, one of which is review of the HSRP by an outside organization.

BNL and the State University of New York at Stony Brook (SBU) have a Memorandum of Understanding that delegates review and approval of human subjects research to the Stony Brook Committee on Research Involving Human Subjects. SBU decided this year to apply for AAHRPP accreditation.

It seemed logical for BNL to apply for accreditation at the same time, since we are collaborating institutions and share an IRB. It was decided to apply for accreditation rather than undergo the OHRP self-assessment, since BNL has already undergone a site visit by OHRP and other reviews by DOE and other outside organizations over the past 10 years.

Both SBU and BNL have begun processing their formal applications to AAHRPP for accreditation.

BNL is dedicated to creating an environment that emphasizes ethical research, promotes the importance of human subjects protection, and ensures that staff and researchers are current on regulations governing human subjects research.Δ

Environment of concern led to accreditation

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Finally, it is based on the premise that education will help to drive continuous improvement. Many of the lapses in research protection can be traced to a lack of knowledge or awareness. For years, widespread educational programs did not exist. Accreditation aims to bring about change through education.

Three steps in accreditation

Three basic steps are involved in the process, which typically takes six months to a year. The first step is a self-assessment that is submitted to AAHRPP. The second is an on-site evaluation by a team of experts who determine whether accreditation standards are met. The third is the review by AAHRPP's Council on Accreditation, which reviews the application, the site visit report and your response, and then approves or disapproves.

As of September 2008, AAHRPP has accredited 138 parent organizations that represent a total of over 600 entities. Among them is Pacific Northwest National Laboratory.

A significant percentage of the nation's medical schools, research-intensive universities, and Department of Veterans Affairs facilities have already attained accreditation, and many more are in the process. Programs in Canada, Korea, and Singapore have also earned accreditation, and international inquiries are on the rise. As a result, AAHRPP is on track both to accredit the majority of U.S. academic health centers by 2010 and to expand AAHRPP's influence worldwide.

The founding members of AAHRPP are:

- Association of American Medical Colleges,
- Association of American Universities,
- Consortium of Social Science Associations,
- Federation of American Societies for Experimental Biology,
- National Association of State Universities and Land-Grant Colleges,
- National Health Council, and
- Public Responsibility in Medicine and Research.

(Parts of this article by Marjorie Speers were first published in *Science and Engineering Ethics* (2005) 11, 53-59.)Δ

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What does it take to get accredited?

The University of Miami found that the process requires a commitment to quality, hard work, and dedication by everyone in the organization.

The Association for the Accreditation of Human Research Protection Programs (AAHRPP) accreditation represents excellence in a human subjects research program that goes beyond regulatory compliance.

The value of accreditation is recognized by the Office of Human Research Protection (OHRP), industry sponsors, other accredited organizations, and the organization that is undergoing the self-assessment process.

by Lynn Smith, Director, Office of Research Compliance, University of Miami

Lynn Smith

So, what does it take to achieve AAHRPP accreditation? It takes a commitment to quality, hard work, and dedication toward the goal of becoming accredited. This dedication must include support from senior management, and an investment of staff and resources must be allocated to this effort.

How much of an investment will be required is dependent upon many factors, including the size and complexity of the organization. Above all, the protection of human subjects should be paramount in the organization's research mission.

All stakeholders should be involved

All stakeholders in the human research protection program (HRPP) should be involved in the accreditation process, including the organizational official, IRB management and staff, research investigators and study teams, and sponsored projects personnel.

Additionally, any ancillary review committees involved in the research program should be involved. This may include pharmacy, legal counsel, radiation safety, biosafety, privacy, and conflict of interest.

During the self-assessment process, be sure to consult frequently with AAHRPP staff. The AAHRPP website includes many tools that are quite helpful, including tip sheets and FAQs on many essential topics. The evaluation instrument is available on the website and is the document that outlines how each standard and element is measured. It is a critical tool for a successful self-assessment. AAHRPP also offers Getting Started Workshops and annual conferences.

The self-assessment process offers the organization an opportunity to educate itself about the current state of its HRPP and the improvements necessary to achieve accreditation. Completing the self-assessment adds value to the HRPP immediately. The organization will evaluate, create, or revise policies and procedures and compare written policies with practice.

Focus first on areas that are not in regulatory compliance. Allow plenty of time and approach the accreditation process as a team. This is not the job for one person! The value added by the self-assessment translates into a stronger HRPP with consistent policies and procedures that reflect the organization's research practices.

Some common pitfalls

So, what stands in the way of achieving accreditation? Some of the common pitfalls include noncompliance with OHRP and Food and Drug Administration regulations, lack of institutional support from the top, or lack of qualified and experienced research professionals in key positions.

Some organizations are simply unwilling to embrace the higher bar of AAHRPP standards. Not establishing a realistic timeline and target completion date for the self-assessment can delay progress significantly. Lack of communication and cohesion among the parts of the organization that must work together in the accreditation process can also derail progress.

Many research professionals from accredited organizations have indicated that the self-assessment was the most beneficial part of the accreditation process. AAHRPP accreditation is fundamentally achievable. It takes a commitment to quality, hard work, and dedication toward the goal of accreditation.

An organization that makes a concerted effort to improve its program through the self-assessment and that works closely with AAHRPP throughout the accreditation process is well on its way to a successful accreditation outcome.Δ

Levine, Fost raise questions about accreditation

"Many requirements imposed by . . . the accreditation process, have little relationship to the protection of human research participants."

Robert J. Levine and **Norman Fost** wrote an editorial in *The Journal of the American Medical Association* (*JAMA*, 2007; 298 (18): 2196-2198) arguing that "Many requirements imposed by federal agencies, and now by the accreditation process, have little relationship to the protection of human research participants."

Both Levine, Yale University Professor of Medicine, and Fost, University of Wisconsin Department of Pediatrics, have received lifetime achievement awards in recognition of their work in protecting human subjects, including awards from OHRP. Together they have 61 years experience as chairs of IRBs.

They said, "The increase in the IRBs' burden is not entirely the responsibility of federal oversight agencies. Part of the problem is self-inflicted, as academic medical centers shifted responsibility for IRB structure and function to senior institutional officials, often with little IRB experience, who made a political judgment that, in order to avoid sanctions, the
prudent course was to impose requirements on the system that are even more stringent than those of the regulatory agencies.

"In addition, a small number of unanticipated deaths of research subjects at prestigious medical centers . . . became causes cèlébres. Even though the relationship of these unfortunate events to IRB responsibilities is uncertain at most, their reporting reinforced cries that the entire system was broken.

"Clearly, the recent demands for increased bureaucratic procedures and their documentation would not have prevented any of these episodes.

Increasing focus on minutiae

"To the contrary, the increasing focus on minutiae has been distracting IRBs from more important substantive issues. Inflexible requirements for adherence to narrow interpretations of every word in regulations and other policies have led to a system that is more concerned with protection of the institution than protection of human research participants.

"The sources of these problems include OHRP and the FDA because they appear to threaten institutions with draconian penalties for minor infractions;
institutional (university and other) administrators acting out of fear that their institution could be the next to have its entire research operation suspended by 'getting caught' in one of these minor infractions; and credentialing and certifying agencies for supporting these excesses by including them in their criteria for accreditation."Δ

Michael Ardaiz named DOE's new Chief Medical Officer


Michael Ardaiz

Michael José Ardaiz is the new Chief Medical Officer for the U. S. Department of Energy.

An occupational physician from Baltimore, he has worked in occupational medicine for 10 years at both Federal and local levels.

He is known for his expertise in a broad range of topics related to public safety occupations and his service as a consultant to both the International Association of Chiefs of Police and the International Association of Fire Fighters.

Prior to joining the Department of Energy, he was employed for 5 years as Medical Director of the Organization of American States on behalf of the Johns Hopkins Department of Health, Safety, and Environment. He previously worked for the Federal Drug Enforcement Administration and Transportation Security Administration.

He received his M.D. degree from the George Washington University School of Medicine and an M.P.H. from the George Washington University School of Public Health & Health Sciences.Δ

Issue No. 17

Former Worker Program screened 52,000

Expansion includes all DOE sites and the now-defunct beryllium vendor companies.

by Mary Fields, Program Manager, DOE Former Worker Program

More than 52,000 people have received medical screenings since the beginning of DOE's Former Worker Program (FWP) in 1993, and the program has been expanded to include those at all DOE sites and the now-defunct DOE beryllium vendor companies.

Mary Fields

The expansion in 2005 and 2006 provided screenings to more former workers through additional regional projects and a national supplemental program. The policy change for beryllium workers ensured that those who no longer have an employer to turn to for beryllium disease testing could receive this important screening.

The FWP, which is managed by DOE's Office of Health, Safety, and Security, provides for medical screenings for former employees to identify adverse health conditions that may have resulted from working at DOE facilities.

The program uses independent health experts through cooperative agreements held by consortia of universities, labor unions, and commercial organizations throughout the United States with expertise in administration of medical programs.

First projects were nuclear facilities

The first projects, initiated in 1996, served seven defense nuclear facilities. The FWP now serves all former DOE federal, contractor, and subcontractor employees from all DOE sites in close proximity to their residences.

Each FWP team focuses on a distinct subset of the former worker population to:

- Obtain rosters of former employees and their updated addresses;
- Advertise through union and DOE newsletters, news media, public meetings, and mailings;
- Develop informational and informed consent materials and ensure review and approval by appropriate Institutional Review Boards;
- Provide medical screening to interested individuals; and
- Refer individuals with suspicious findings for follow-up medical testing and, if applicable, to the Department of Labor-run Energy Employees Occupational Illness Compensation Program.

Approximately 470,000 former workers have been invited to participate. More than 52,000 have been screened, and more than 6,100 have been rescreened.

However, there are still many former workers who have not been served by this program. It is the responsibility of all of us who manage and implement this program to ensure that we continue to reach out to as many former workers as possible and redouble our efforts to assist all the workers who wish to take advantage of this program's benefits.

Information about the program is at **http://www.hss.energy.gov/HealthSafety/FWSP/formerworkermed/.**

Screenings are conducted by, among others, Boston University (collaborating with the University of California, San Francisco); CPWR-The Center for Construction Research and Training, in conjunction with its partners, University of Cincinnati, Duke University, and Zenith Administrators; Drexel University (collaborating with the University of Texas Health Science Center at Tyler); Johns Hopkins Bloomberg School of Public Health; the Medical University of South Carolina; Oak Ridge Associated Universities, in collaboration with Comprehensive Health Services, National Jewish Health, and Occupational HealthLink; Queens College City University of New York; United Steelworkers; and University of Iowa College of Public Health..Δ

More than 52,000 have been screened, and more than 6,100 rescreened. However, there are still many formers workers who have not been served by this program.

Meetings

Fifth International Conference on Ethical Issues in Biomedical Engineering
April 3, 2009
New York Marriott Renaissance Plaza
For information, see http://www.bioethics.net/events.php?viewEvent=5777

Annual Meeting of the American Society for Bioethics and Humanities
October 15–18, 2009
Hyatt Regency Capitol Hill, Washington, D.C.
For information, see **http://www.asbh.org/meetings/annual/index.html**

PRIM&R 2008 Advancing Ethical Research Conference
Nov. 14–16, 2009
The Gaylord Opryland Resort & Convention Center, Nashville, TN
For information, see **http://www.primr.org**

Conflicts of interest

Policy gaps found in how IRBs address the issue

Most IRBs explicitly prohibit a conflicted member from participating in discussion and voting, but few explicitly prohibit serving as a reviewer or extend their policies to cover IRB staff, according to an article in **The Hastings Center's** *IRB: Ethics & Human Research* (http://www.thehastingscenter.org/Issues/Default.aspx?v=1416).

The article, "Conflicts of Interest in Research: How IRBs Address Their Own Conflicts," is written by **Leslie Wolf** and **Jolanta Zandecki**.

They conducted the study to determine whether institutions address conflicts of interest among their IRB members and staff, and, if so, in what ways. They analyzed policies for 121 U.S. medical schools whose research is funded by the National Institutes of Health.

About three-quarters of the schools studied have written policies that address IRB conflicts of interest, and almost 80 percent of them defined the term, although their definitions varied substantially.

The findings illustrate important gaps in these policies, the authors say. A few policies even conflict with federal requirements. They suggest that more specific policies might improve consistency and increase confidence in the integrity of the review.

Larger incentives don't lead to accepting higher risk levels

Monetary incentives are increasingly used to help motivate survey participation, and Research Ethics Committees have begun to ask whether, and under what conditions, the use of monetary incentives to induce participation might be coercive.

An online vignette-based study concludes that larger incentives do not induce research participants to accept higher risks than they would be willing to accept with smaller ones.

The Journal of Empirical Research on Human Research Ethics (Vol. 3, No. 2, June 2008) reports the findings in an article by **Eleanor Singer** and **Mick Couper**, both of the University of Michigan, "Do Incentives Exert Undue Influence on Survey Participation? Experimental Evidence."

JERHRE is at:
http://caliber.ucpress.net/loi/jer.

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Protecting Human Subjects

This newsletter is designed to facilitate communication among those involved in emerging bioethical issues and regulatory changes important to both DOE and the human subjects community.

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