

Lead Report

Outlook 2012

Compliance Efforts, Big Regulatory Changes, International Research Top Issues This Year

The sluggish economy and efforts to cut government spending are likely to dominate an election year in a partisan political environment, and these overarching issues will have a significant effect on medical research, according to experts interviewed by BNA.

Research institutions will have to deal with these political and financial uncertainties as they work to comply with new conflict-of-interest requirements, mull the possibility of changes to the Common Rule for protection of human research subjects (45 C.F.R. Part 46), and address other important issues, they said.

"All the things we work on every day—advocacy for research for health—are going to be impacted, as is the entire research community . . . by the public frame[work] that we all operate in," Mary Woolley, president of Research!America, told BNA Dec. 8, 2011. "It's about the economy, it's about health care," and specifically the quality, access, and cost issues that have upset the public and policymakers, she said.

All of that angst and concern about both the economy and health care are playing out in an election year, she said, and candidates for office are emphasizing their differences as the issues become more politicized. "So they're not looking for points of agreement. That's really damaging potentially for research, especially around policy issues in research," Woolley said.

Science historically has benefited from bipartisanship, she said, citing as an example the 40th anniversary of the signing of the National Cancer Act on Dec. 23, 1971. However, such bipartisan efforts are less likely to happen in 2012, Woolley said.

"It's very concerning because there's nothing inherently political about science," Woolley said. "It's not a Republican issue and it's not a Democrat issue. We don't like to see splits along party lines on issues that there's no reason for splitting."

The Research!America president discussed what she felt would be the top legal, regulatory, and policy issues for medical research in 2012. Others commenting included Ann C. Bonham, chief scientific officer of the Association of American Medical Colleges, and members of the *Medical Research Law & Policy Report* editorial advisory board. Compliance efforts—specifically related to the new financial conflict-of-interest regulations as well as cost principles for research grants—came up most frequently. Also mentioned were the advance notice of proposed rulemaking (ANPRM) on the Common Rule, possible declines in research funding, and international research.

Conflict-of-Interest Regulations. After more than two years of deliberation, the National Institutes of Health released in August 2011 the first sweeping set of

changes to the financial conflict-of-interest regulations since 1995, formally called "Responsibility of Applicants for Promoting Objectivity in Research for Which Public Health Service Funding Is Sought and Responsible Prospective Contractors" (42 C.F.R. Part 50; 45 C.F.R. Part 94) (10 MRLR 587, 9/7/11).

The new final rule lowers the threshold triggering reporting requirements from \$10,000 to \$5,000; requires investigators to disclose all significant financial interests that relate to the their institutional responsibilities, not only those related to the research projects they are conducting; adds public reporting and training requirements; and requires more reporting by the institution to the funding agency.

"I think the largest issue by far is going to be the implementation of the Public Health Service conflict-of-interest regulations," Mark Barnes, a MRLR board member and Harvard University's senior associate provost and chief research compliance officer, told BNA Dec. 16, 2011. "These regulations . . . fundamentally change our approach to reporting and analyzing financial interests. . . . They impose very large and new obligations on hospitals and academic institutions that receive PHS funding, and right now universities and hospitals are scrambling to try to understand the regulations and then to get them implemented."

"You can't wait until July and August to do this . . . If you don't have [faculty's] annual financial disclosures in hand before Aug. 24, you can't submit their grants."

MARK BARNES, HARVARD UNIVERSITY

Carol Pratt, a MRLR board member and attorney at K&L Gates in Portland, Ore., whose practice focuses on regulatory issues associated with research, told BNA Dec. 15, 2011, that the revised financial conflict-of-interest rules are a bellwether of greater financial disclosure requirements from the government.

"The movement is toward having more reporting of financial interests that could potentially bias the outcome of results or potentially create risk to the subjects" of research, she said.

Ernest D. Prentice, a MRLR board member and associate vice chancellor for academic affairs at the University of Nebraska Medical Center, expressed similar thoughts.

"This country is moving toward much more transparency in terms of the impact of financial interests on the integrity of the way we conduct clinical research," he said Dec. 13, 2011.

With a compliance date of Aug. 24, Bonham of AAMC said in written comments to BNA, institutions are work-

ing diligently to interpret the financial conflict rules and revise their policies, practices, and systems to meet the implementation date.

"The medical research community is committed to ensuring that clinical decisions and research conclusions are based on objective, unbiased data but is also struggling with marshaling the resources that will be required to comply with the administrative processes required by the regulations," Bonham stated in comments e-mailed Dec. 13, 2011.

Compliance Advised by June, Not August. Although NIH allowed a full calendar year to come into compliance with the new financial conflict-of-interest rule, Barnes said, institutions must get these new systems in place by the end of the academic year, or June 30 at the latest, as most faculty leave campus after June.

"You can't wait until July and August to do this," Barnes said. "It's faculty who have to do this, and it's faculty or medical staff who are the ones who are directly affected by this. And if you don't have their annual financial disclosures in hand before Aug. 24, you can't submit their grants."

Barnes said institutions must for the first time coordinate disparate systems: the conflict-of-interest analysis and reporting system on the one hand, and the sponsored research system on the other, to implement these new rules.

Physician Payments Sunshine Act. While the NIH rule requires investigators to disclose financial interests to their institutions, and institutions in turn must report those disclosures to NIH, Pratt said, the Physician Payments Sunshine Act works in the other direction, requiring manufacturers to disclose payments made to investigators.

The Centers for Medicare & Medicaid Services released a Sunshine Act proposed rule Dec. 14, 2011, that would require applicable manufacturers of drugs, devices, biologicals, or medical supplies covered by Medicare, Medicaid, or the Children's Health Insurance Program to report annually to the secretary of health and human services certain payments or transfers of value provided to physicians or teaching hospitals (10 MRLR 855, 12/21/11). These disclosures would be made publicly available.

"The feds are going to have parallel data about the same apple from two different sources," Pratt said. "If they have an infrastructure for coordinating, they will be able to cross-tabulate and see if the other data are consistent. And that's going to create a lot more compliance risks and pressure."

Prentice also cited the Physician Payments Sunshine Act as an important issue for medical research in 2012.

"We're not doing a great job of managing conflict of interest in the private sector. I think we're going to see more movement in the future in that direction," he said. "We are doing a much better job in academia. We have become very strict."

Sometime in the future, Prentice said he expects the stringency of the NIH rules to affect the private sector. Currently, there are differences between financial conflict standards of NIH and the Food and Drug Administration, he said.

"It's not going to be immediate. I don't think there's going to be a big push to get FDA to adopt really tough conflict-of-interest rules. But I think we're moving in that direction, maybe five years from now we might see

if they become a little bit closer in terms of their stringency," Prentice said.

"It's very clear that we are operating in an environment where noncompliance is less tolerated than it was before."

ERNEST D. PRENTICE, UNIVERSITY OF NEBRASKA MEDICAL CENTER, ON FDA

Robert J. Kenney Jr., a MRLR board member and an attorney with Hogan Lovells in Washington, told BNA Dec. 16, 2011, that in addition to CMS and NIH, medical journal publishers and Congress remain involved in financial conflict of interest.

"There's a tremendous amount of attention being given to the effect of financial disclosures and on the conduct and reporting of research," according to Kenney, a lead partner in Hogan Lovells' federal research practice. "I just have to think that this is going to continue to be a big issue on many fronts in 2012 and beyond."

Compliance, Enforcement. Additional scrutiny on compliance and enforcement of the grant administration rules by the federal government also frequently came up as a big issue in 2012. Harvard's Barnes said the HHS Office of Inspector General is likely to focus on time and effort reporting of federal research grants as well as the selection and monitoring of subcontractors in federally funded projects.

"The OIG has flagged these as being high on its list for examination and compliance," Barnes said, especially because of the increase in grant awards issued through economic stimulus funding. "I think we're going to see additional scrutiny in that area."

Kenney of Hogan Lovells also mentioned effort reporting, specifically the work of the A-21 Task Force, an interagency research and science effort to improve policies in the White House Office of Management and Budget Circular A-21, "Cost Principles for Educational Institutions." The task force was formed out of the Subcommittee on Social, Behavioral and Economic Sciences of the National Science and Technology Council Committee on Sciences.

"The A-21 task force is going to be an important development in 2012. For many years, the research university community has been complaining very justifiably about the burdens and difficulties that are imposed on them by the federal cost principles," Kenney said. "Those burdens are partially cost burdens because you have to make an investment in administrative infrastructure in order to comply with these requirements. But they're also a burden on researchers who feel that they're often distracted from their main mission with attention to things that are not as important as the research itself. So it's certainly a legitimate concern."

Kenney added that there seems to be a fair amount of optimism that the task force will recommend changes to the cost principles, specifically in effort reporting, which has been identified as a particular area of burden. The Council on Governmental Relations proposed elimination of the effort reporting requirement for uni-

versities with publicly funded grants or contracts in a November 2011 letter to the task force (10 MRLR 822, 12/7/11).

"Since so much of biomedical research is funded by federal money, and since so much of research is done by universities, these changes to the university cost principles—if they are going to happen—will be quite a significant development," Kenney said.

Barnes expressed similar thoughts.

"If that A-21 task force comes out with [recommendations] that are accepted by OMB, then we're going to be faced in the second half of the year with implementing those things, which could be dramatic," he said.

Prentice said FDA also has enhanced its research-related enforcement efforts.

"It's very clear that we are operating in an environment where noncompliance is less tolerated than it was before, which is a good thing as far as I'm concerned," he said. "I have no problems whatsoever with enhanced enforcement. What I worry about is with the federal government, and the budget deficits, and the cost cutting, what will happen to regulatory agencies such as the FDA?"

He expressed concern that potential cuts to FDA's budget could translate to cuts to the agency's biomonitoring divisions, which could affect the ability of the agency to enforce the regulations.

"They're already short staffed, so what would that mean? I would worry about that," he said.

"The research money that comes in to pay for the laboratories doesn't help to pay for the compliance."

ROBERT J. KENNEY JR., HOGAN LOVELLS

Kenney said while there definitely are trends in the government toward greater enforcement, there are simultaneous efforts such as the A-21 task force to reduce regulatory burdens.

"Of course, all of this is in the context of probably less research money coming in to many institutions. The research money that comes in to pay for the laboratories doesn't help to pay for the compliance. So the institutions are relying on the indirect cost money and other sources of funding to support the increased cost of compliance," Kenney said. "But as the research funding comes in, if it is flat or less—at least for some areas or for some institutions—of course the indirect cost funding will be less, and there will be that much less to use to support the infrastructure. So it's not a hopeful picture all around."

Further, Kenney said, agencies that fund research are taking steps "to try to squeeze grantees in terms of reimbursement" by limiting indirect cost recovered and limiting the amount that can be recovered in direct costs.

"It's not too surprising, given the scarcity of research funding, that agencies would try to do everything they can to get the most research for the dollar, but that's an issue that I think is going to be of concern for awhile."

Funding, Budget Concerns. Funding and budget concerns also continue to be a top concern in 2012.

"Appropriation decisions affecting funding for NIH, as well as for [the Centers for Disease Control and Prevention, Agency for Healthcare Research and Quality, Health Resources and Services Administration], and the Department of Veterans Affairs research programs, coupled with increasing burden on state funding and clinical margins, will likely require academic institutions to develop new business models for the research enterprise to focus on impact, quality, and sustainability during times of unprecedented economic constraints," Bonham of AAMC stated.

She said that, based on Congressional Budget Office estimates, the automatic budget enforcement procedures specified in the 2011 Budget Control Act would result in a 7.8 percent decrease in nondefense discretionary spending, which includes the HHS budget.

"While these cuts would not take effect until 2013, institutions will likely take them into account [during] scenario planning in the next year to sustain their medical research mission," she said.

Research!America has raised the issue of research funding and concerns about flat funding for years, but Woolley said the concern is more severe now than ever because of the public outcry over the federal debt.

"We've never seen that before," she said. "It's so big this year that we got a downgrading in our ranking," Woolley said, referring to Standard & Poor's historic decision last August to downgrade the federal government's credit rating for the first time. "But we could get the same downgrading in our scientific ranking—if there were such a thing—and we're pretty close to that right now."

Woolley said the looming cuts come as nations such as China ramp up their support for research and development in proportion to their gross domestic product because they see an opportunity as leading nations in science struggle.

"Our concern is that the U.S. could go from world class to second tier in not too many years," Woolley said. "We're extremely concerned about this."

Changes to the Common Rule. While it is unclear when and if the HHS Office for Human Research Protections will take any formal action on proposing changes to the Common Rule, the significance of the ANPRM released in 2011 carries this over into 2012 as a top issue (10 MRLR 513, 8/3/11).

OHRP "went on out a limb. It has some pretty aggressive positions in there," Jennifer S. Geetter, an attorney with McDermott Will & Emery LLP, Washington, told BNA Dec. 8, 2011. "Who knows how many of those will survive two more rounds of rulemaking, but I think anyone who's taking a close look at this sees that this is not an attempt to tinker around the edges or make a few targeted updates. It's really [asking], 'If we were writing this rule for the 21st century, what would it say?' That alone is a major development."

One significant revision would be the proposal to expand the reach of the Common Rule to any hospital that receives any federal funds in connection with research, according to Geetter, whose practice includes emerging biotechnology and safety issues, advising on research-related matters, conflicts of interest, and scientific review and research misconduct.

"So even if you were doing a study that was privately funded, if you otherwise have federally funded human subjects research, you'd have to comply with the rule, and the enforcement of that agency," she said.

Because most hospitals receive at least some federal funds, even as a subrecipient of a grant, Geetter said, if that particular provision goes through, the new rule essentially would apply to all human subjects research.

"So in general people should assume that this is how human subjects research will get done," she said.

Bonham also cited the ANPRM as a top issue for 2012. She said other proposed changes in the rule also would be significant, including:

- calibrating the research review requirements with risks,
- standardizing data security standards,
- requiring written consent for research use of biospecimens collected for clinical purposes,
- revising requirements for expedited review and exempt studies, and
- streamlining institutional review board review, among other issues.

"Depending on the how these proposed changes are addressed, new regulations could either accomplish the goals of the ANPRM to protect subjects and reduce burden, or could increase burdens without meaningfully increasing protections to subjects," she stated in her written comments.

For example, the proposed requirement for a single IRB of record for multi-site trials could significantly lessen institutional burden, provide more consistent protections for subjects, and reduce delays in approval processes, as long as it is implemented appropriately with specific guidance on IRB and site responsibilities, Bonham stated.

She said OHRP in the past has taken enforcement actions against institutions that had delegated IRB review to another entity. Given that history, Bonham said, OHRP must provide adequate guidance on any requirement for a single IRB of record for multi-site studies. Otherwise, institutions may feel the need to create "shadow" IRBs, which would further increase the burden of compliance and most likely slow the process for approval of human subject research, she said.

Barnes flagged as controversial a proposal that would require a general consent for future research use of biological specimens or data at the time of the first interaction with either the patient or research participant.

"It would change our consent processes for both patient care and research across the board," he said. "I think what happens to that as well as other ANPRM proposals is going to take up a lot of time and cause a lot of controversy in 2012."

Prentice also identified the proposed changes to the informed consent requirements for future research use as a concern. "That would be very difficult. That would hamstring a lot of research," he said.

Prentice said the ANPRM is number one on his list of top issues for 2012.

"Not so much that I think it's going to get passed in the next year, but I think it [has] perhaps precipitated a dialogue about what needs to be changed, and what would be a better system," he said.

With 17 federal departments and agencies signed on to the Common Rule, Prentice said he was pessimistic that all those government entities would agree to the changes.

"Particularly in an election year where Congress seems to be operating in a paralytic fashion," he said, adding that regardless of the election results, agency heads are likely to change. "I'm just not optimistic. But overall it's quite an impressive proposal."

Prentice said he supports the proposal to eliminate the requirement for yearly, continuing review of minimal risk research.

"That's a significant workload on the part of IRBs and investigators with no useful gain in terms of human subject protection. That's just kind of nuts," he said. Prentice added that he liked the proposed idea of requiring a single IRB of record for multi-site studies but did not believe it was practical.

"If we could figure out a way to do this it would certainly decrease the cost of clinical trial review. How they would do it, I have no idea," Prentice said.

However, he did not support the proposal to allow investigators to register studies that would be excused from review under the Common Rule.

"That's fraught with all kinds of problems because investigators are going to figure everything should be excused from the Common Rule. So that's not a good idea," he said.

"There are some good elements, some impractical elements, and there are some bad elements," in the ANPRM, Prentice said. "But I think it's great we've got this dialogue going."

International Research. International research, a perennial entry on the list of most significant medical research issues, also was cited by experts as a top issue in 2012.

Kenney said that while on the one hand it is considered less expensive to conduct research overseas, there also are arguments that it can be more expensive due to the administrative costs of carrying out the research abroad, ranging from the need to comply with U.S. rules and adapting to a different cultural structure to employment and tax issues. He said these issues can create enormous costs, especially because research institutions generally are in the beginning stages of learning how to conduct research abroad.

"The trend to doing research overseas is so powerful that there's no question all of those issues are going to have to be addressed and the urgency of addressing them is that much greater," he said.

Prentice said there needs to be an effort to enhance educational efforts on research ethics and regulations internationally. He noted efforts such as the [Collaborative Institutional Training Initiative](#), a collaboration between the University of Miami and the Fred Hutchinson Cancer Research Center to develop a web-based training program in human research subject protection.

"We've seen a huge migration of clinical research globally. I think it's important that steps be taken to ensure that the research that's being conducted in India, or China, or elsewhere, adheres to appropriate ethical and regulatory standards. And I know that there's lots of concern that that doesn't necessarily happen," Prentice said. "Let's face it, they're not up to where the United States is in terms of the ethics and regulation of research because it took us a long time to get to where

we are. So it's hard for me to believe that they're there. And I think it's important that pharmaceutical companies, CROs [clinical research organizations], FDA, and any government agency recognize that if they're going to be doing clinical research, they have an absolute obligation to protect the rights and welfare of human subjects."

Biospecimens, Personalized Medicine. Biospecimens and data also continue to be a top issue for 2012.

"It's an important issue scientifically but it's also an important issue culturally and socially. And it's an issue we don't have good answers for yet," Geetter of McDermott Will & Emery said. "It's an area that's in tremendous flux. At the same time, it's an area that's really at the heart of some of the more exciting biomedical innovations. So at the very moment when industry and research centers are relying more and more on existing stocks of data and tissue is the exact same time that we as a society are just not sure exactly how we want to do it. It's obviously on people's minds."

Pratt noted that there have been significant regulatory proposals, both through the ANPRM for the Common Rule as well as proposed changes to the privacy rule under the Health Insurance Portability and Accountability Act, that would affect biospecimens and the issue of secondary use of data (10 MRLR 859, 12/21/11).

The K&L Gates attorney also talked about biospecimens in the context of personalized medicine, which she expects to be a big issue in 2012.

"This is where the market is. It's also where the R&D [research and development] activity is in the sense . . . that the pipeline of blockbuster drugs is on the wane, and we're moving more in the direction of biologics and customized therapeutics," Pratt said.

Personalized medicine in turn raises a whole range of topics, from patent reform to exculpatory language, biospecimens, and secondary use of data, she said.

"When you connect all these, the picture is moving us fairly methodically in the direction of personalized medicine so you have to create a feasible regulatory infrastructure for the fundamental pillars of personalized medicine R&D," Pratt said.

Regenerative Medicine. Bonham said the U.S. District Court for the District of Columbia decision in *Sherley v. Sebelius* (D.D.C., No. 1:09-cv-01575-RCL, 7/27/11), rejecting a challenge to federal funding of human embryonic stem cell (hESC) research, will continue to make regenerative medicine an important issue in 2012. The plaintiffs seeking to block federal hESC research funding have filed an appeal of the decision with the U.S. Court of Appeals for the Federal Circuit (10 MRLR 653, 10/5/11). A briefing schedule for appeal recently was published by the court, with final reply briefs due on March 12.

"The AAMC, working with the Coalition for the Advancement of Medical Research, has been actively involved in filing amicus briefs that uphold the ability of the National Institutes of Health to support this promising research," Bonham said.

Further, she noted that in November, Geron Corp. announced it would stop a study of use of hESCs to treat spinal cord injuries due to anticipated difficulty in raising private and other capital for support of this research (10 MRLR 759, 11/16/11).

"This may trigger new policies regarding stem cell research undertaken by private industry as well that are funded by the federal government," Bonham wrote.

Comparative Effectiveness Research. Comparative effectiveness research, and the work of the Patient Centered Outcomes Research Institute (PCORI), is another issue Bonham cited as important for the coming year.

"PCORI has placed an increasing emphasis on the perspectives and values of patients throughout the research process from the selection of the research questions to the dissemination of the research results. The priorities established by PCORI place an increased emphasis on outcomes that people care about including survival, function, and quality of life, the importance of studying the benefits and harms of interventions in real-world settings with previously underserved groups, and important attention to implementation or dissemination of the research findings," Bonham stated. "The funding policies around these priorities will likely have a positive effect on comparative effectiveness research that goes beyond drugs, to include preventive strategies, health systems, and other comparative interventions and that will guide research in 2012 to focus on engaging diverse groups of persons into the comparative effectiveness research agenda."

Community-AMC Research Partnerships. Geetter said the emergence of community and regional health systems engaging in research also is likely to be an important issue in 2012. Historically, she said, research largely was part of the academic model. However, in recent years, she said, there has been a tremendous amount of interest at the community and regional health system levels in research, both because the doctors want to conduct the research and because the local health providers are looking for competitive advantages.

"If you're going to do a little research, it doesn't mean you get a little compliance."

JENNIFER S. GEETTER, McDERMOTT WILL & EMERY LLP

"As the general health system landscape changes [in ways] having nothing to do with research, we're likely to see a continuation of research happening increasingly at the community and regional health levels, either on a stand-alone [basis] or in partnerships with academic medical centers," she said. "While that is in general a plus for the patients and subjects and for the research enterprise, it does mean that institutions that have a lot less familiarity with research are going to need to figure out how to scale up their research programs. That is a real challenge for institutions of that size."

She said a number of challenges exist because there are certain aspects of compliance that are required no matter what the size of the research program may be.

"If you're going to do a little research, it doesn't mean you get a little compliance," she said.

Geetter said she and her colleagues work with community and regional health systems to achieve excellence within their research compliance programs in a way that fits the size of the health center.

Health Care Disparities. Bonham said continuing disparities in the prevalence of disease burden and access to care will have an impact on research. She said this is an increasingly urgent issue, “not only for social justice, but also for public health and in the quest to establish and sustain more effective [health care] delivery systems.”

“While these are not policies or regulations, the increased attention to research may trigger new policies to focus on research to develop an evidence base for addressing disparities—through fundamental discovery, quality measures, or health outcomes,” she said.

Referring generally to the medical research enterprise, Prentice said, “These are heady issues that we face in 2012 and beyond.”

By JEANNIE BAUMANN

Human Subject Protection

Menikoff Says Common Rule, Consent, International Research Top Issues in 2012

While federal health officials continue an ambitious effort to modernize human subject protection regulations in 2012, the Health and Human Services Office for Human Research Protections will keep developing guidance under the existing regulations in areas that need clarification, according to the office’s director.

Jerry Menikoff, who has lead OHRP for more than three years (7 MRLR 678, 11/5/08), spoke to BNA Dec. 12, 2011, about what he believes the top subject protection issues will be in 2012. He identified three key areas:

- the advance notice of proposed rulemaking (ANPRM) to modernize the “Common Rule” for protection of human research subjects (45 C.F.R. Part 46),
- informed consent, and
- international research.

The OHRP director said he was expressing his own views and that his comments did not reflect any official statement from HHS.

Common Rule Revisions. The first key issue Menikoff identified was the ANPRM issued in July (76 Fed. Reg. 44512, 7/22/11; 10 MRLR 513, 8/3/11), the first effort to make significant regulatory changes since the adoption of the Common Rule in 1991. The ANPRM sought feedback on 74 questions about issues such as requiring a single institutional review board of record for multisite studies, calibrating the level of review to the level of risk, and establishing mandatory data security and information protection standards for all studies involving identifiable or potentially identifiable health information. OHRP reported in December that it received 1,112 comments on the ANPRM (10 MRLR 813, 12/7/11). Menikoff said OHRP is in the process of evaluating the comments.

“We’ve gotten many, many comments, very helpful comments,” he said. “It seems reasonable that during 2012 there will be some follow-up from all of this. At this point, it’s a little hard to predict exactly where this will go, but the notion that the rules would benefit from

some revision, that notion probably isn’t going to go away very quickly.”

He said the specific timing of any action is difficult to forecast.

“As to the timing, that’s really, really hard to predict,” he said. “It’s a complicated thing trying to change the Common Rule . . . there would be a lot of guesswork [in predicting] when something might come out.”

The next step would be either to maintain the status quo and keep existing regulations or issue a proposed rule for another round of comments. He added if HHS moved forward with a proposed rule—known formally as a notice of proposed rulemaking or NPRM—it could differ from the ANPRM.

“Certainly one option is to keep the status quo, not do anything,” Menikoff said. “On our side, there’s a desire to move forward. But again things are still being reviewed.”

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JERRY MENIKOFF, OHRP DIRECTOR

New Guidance Still to be Considered. Even though HHS is focusing on changing the regulations, Menikoff said, OHRP will continue to make clarifications on the rules as they apply now.

“I certainly wouldn’t say we have shut down the possibility of issuing new guidance. In fact, that’s not true. We’re looking at a variety of issues relating to current guidance,” he said.

What happens specifically with respect to new guidance, Menikoff said, will depend on what is going on with the follow-up to the ANPRM and any decision on issuing a proposed rule.

“We definitely have not put everything on hold in terms of only pursuing revisions to the regulations and not doing anything apart from that,” Menikoff said.

Improving the effectiveness of the system for protecting human subjects has been a top issue for Menikoff since he became OHRP director. He cited this as the top issue both in 2010 and 2011 in similar interviews with BNA (9 MRLR 9, 1/6/10; 10 MRLR 8, 1/5/11).

“Certainly it’s an area of my interest, but one of the reasons I was interested in it was precisely because plenty of other people also had been looking at these regulations over the years and finding that there were areas that could benefit from change,” he said.

While guidance documents are one avenue for federal entities to make such changes, Menikoff said, there are limits to what can be accomplished through such documents.

“It’s interesting looking at how many people have often said, ‘What we really need are the changed regulations, but of course since it’s the Common Rule, we’re not going to be able to do it.’ So it’s nice to have that [ANPRM] on the table,” Menikoff said.

The OHRP director added that one of the most positive responses he has heard is that regardless of the ul-