

gist was permanently barred from conducting medical research on humans after the Food and Drug Administration (FDA) discovered he had violated federal rules concerning patient safety. Fenster was notified in March (RRC e-mail, March 30, 2006) that the FDA had found "objectionable conditions" and gave him 15 days to respond. Essentially, Fenster's response to the FDA was that he attributed the problems to "simple clerical errors." Among the FDA's findings surrounding Fenster's activities: (1) a physician not approved as a study physician implanted pacemakers in three people and tried to implant one in a fourth; (2) screening and enrollment logs of subjects were not maintained; and (3) Fenster failed to make a timely notification to the IRB when a subject died. **Link:** <http://www.tucsoncitizen.com/daily/local/14253.php>. (6/22/06)

◆ **Jon Sudbo** admitted earlier this year to faking research data included in an article he published in the British scientific journal *The Lancet*; evidently that admission was just the beginning. A Norwegian commission, appointed to investigate the cancer researcher, found that most of Sudbo's work is invalid because of falsified data. The commission decided that Sudbo had acted alone, according to the Associated Press, and that none of the approximately 60 co-authors were involved in the fraud. **Link:** <http://www.mercurynews.com/mld/mercurynews/living/health/14945846.htm>. (7/6/06)

◆ **Steven Anthony Leadon**, a former professor of radiation oncology at the University of North Carolina (UNC) has entered into a Voluntary Exclusion Agreement (VEA) with the Department of Health and Human Services following a university investigation of scientific misconduct and further analysis conducted by ORI. Leadon, while supported by grants from the National Cancer Institute, was found to have falsified DNA samples and constructed falsified figures for laboratory experiments. Leadon claimed findings of defects in a DNA repair process that involved rapid repair of DNA damage in the transcribed strand of active genes. The falsifications were included in four grant applications and in eight publications and one published manuscript. Leadon maintained that he did not engage in scientific misconduct and attributed the problem to a systematic error that was introduced into the experiments. He stated that he entered into the VEA because of an inability to sustain the financial burden of further legal proceedings. The five-year exclusion covers contracting or subcontracting with any agency of the federal government and participating in any Public Health Service advisory capacity. Leadon also will submit letters of retraction to the journals involved. **Link:** <http://ori.dhhs.gov/misconduct/cases/Leadon.shtml>. (6/22/06)

◆ **Dalibor Sames**, who had retracted two scientific papers in March (RRC e-mail, March 16, 2006), announced he will retract four more. The Columbia University chemistry professor was the senior author on all the papers in question, according to the *New York Times*. A former graduate student under Sames, Bengu Sezen, is credited with performing most of the experiments described in the papers. Sames said independent researchers have been unable to reproduce the original findings. The latest retractions concern one paper published in 2003 in the journal *Organic Letters* and three others in *The Journal of the American Chemical Society* in 2002 and 2003. Columbia also has opened an investigation into why the experiments were not reproducible. **Link:** <http://www.nytimes.com/http://pubs.acs.org/cen/news/84/i25/8425papers.html>. (6/22/06)

◆ **Lingjie Zhao** was found to have engaged in research misconduct by the ORI. Zhao, a former doctoral student at the University of Iowa, falsified research records included in a manuscript submitted for publication in *Cancer Research*, drafts of her work reported in the lab, and drafts of her work reported to her dissertation committee. Zhao, whose research was supported by an NIH grant, entered into a Voluntary Exclusion Agreement for a period of three years beginning on June 3, 2006. The voluntary agreement includes excluding Zhao from any contracting or subcontracting with any U.S. government agency and from serving the Public Health Service in any advisory capacity. **Link:** <http://frwebgate4.access.gpo.gov/cgi-bin/http://ori.dhhs.gov/misconduct/cases/Zhao.shtml>. (7/13/06)

◆ **J. Reece Roth**, a retired University of Tennessee at Knoxville professor, is being investigated by the FBI on suspicion that he shared sensitive research information with foreign countries. Roth denies the allegations and claims that the research he shared with two Chinese universities is publicly available online. The research in question is tied to a subcontract with the U.S. Air Force. **Links:** [http://www.wate.com/Global/story.asp?S=5137476&nav=menu7\\_2](http://www.wate.com/Global/story.asp?S=5137476&nav=menu7_2) and <http://www.insidehighered.com/news/2006/07/12/secret>. (7/13/06) ◆

## Survey Indicates Researchers Don't Have Enough Research Time

What do researchers do? According to the preliminary results of the "Faculty Burden Survey," researchers claim they only spend 58 percent of their research time actually doing research; the remaining 42 percent goes to administrative tasks.

The survey, the first of its kind to focus on research, was undertaken by the Federal Demonstration Partner-

### *The Researcher's Top Administrative Burdens*

1. Grant progress report submission
2. Personnel hiring
3. Project revenue management
4. Equipment and supply purchases
5. Institutional Review Board protocol approvals and training
6. Training personnel and students
7. Personnel evaluations

*From preliminary results of the Federal Demonstration Partnership "Faculty Burden Survey"*

ship to determine the extent of the administrative burden that faculty assume when they apply for and receive federal funds, and what impact that burden has on conducting research.

Researchers were asked to rank 24 specific burdens — proposal writing was not included.

The data analyzed came from 6,081 full-time faculty, either principal investigators or co-investigators on federally funded projects in the 2004 academic year.

The majority of the respondents were from highly research-intensive institutions; 71 percent were from public institutions. See a list of the top seven burdens from the "Faculty Burden Survey" in box above.

Dr. Robert Decker of Northwestern University, who coordinated the massive effort, reported that with more than 250 pages of "anecdotal discussion" to analyze, as well as further analysis of the data, there is much more to be learned from the survey. Full results and analyses will be published this fall. ♦

## **NIH Electronic Submissions**

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"The eRA processing ability and software continue to improve," Ralbovsky said. "NIH has received applications submitted to Grants.gov using Pure Edge forms, from institutions who have developed system-to-system solutions, and from commercial service providers."

Marcia Hahn, director of NIH's Division of Grants Policy, said that from the outset the transition strategy was to take "the lowest fruit on the tree [and] start on a smaller scale." The transition began last December and gradually worked through the "lower fruit" giving institutions and other applicants a chance to adapt to the whole process, and the strategy allowed NIH to "work out the kinks" that occur in transition events, Hahn said.

For example, "we did a major [policy] change in spring, and all that [related to the old requirement] had to be removed" from the electronic process. Hahn was referring to the first week of April when NIH made changes in the electronic submission process and eliminated the requirement that the principal investigator's (PI) signature be on grant applications, progress reports, and prior approval requests. This was replaced by an institutional compliance requirement: the applicant organization secures and retains a written, signed assurance from the PI and provides it upon request.

Because of the change in the PI signature requirement, NIH and the Agency for Healthcare Research and Quality no longer require eRA Commons verification of applications submitted through Grants.gov.

### **Better-Educated Users, Staff**

Ralbovsky emphasized the importance of all the people in all the entities — Grants.gov, NIH, institutional — involved in the transition.

"Aggressive communications efforts have resulted in better-educated users and staff," he said. "Offices of sponsored research have risen to the occasion, proving themselves to be well-prepared for electronic submission. Now many applications are going through on the first try."

Institutions' increased familiarity with the electronic submission process allows NIH to go forward faster.

"The eRA Help Desk is much more accessible," Ralbovsky explained. "Call volume decreased dramatically as a result of many factors, including a strong outreach program, improved error messages, and re-evaluation of business rules enforced by [the] system."

Ralbovsky concluded, "There is a long way to go and some tough challenges ahead, but the continual improvements are very encouraging." (See NIH Grants.gov Transition Plan schedule on p. 11)

**Link:** <http://era.nih.gov/ElectronicReceipt/>.

**Note:** For those seeking training or a refresher course in electronic submission, check out NIH's training site, <http://era.nih.gov/ElectronicReceipt/training.htm>. Among the tools is a video overview of the electronic submission process, which Marcia Hahn said had just been re-taped to "refresh it." ♦

### *Links in the News*

Documents referred to in this issue are posted at [www.ReportonResearchCompliance.com](http://www.ReportonResearchCompliance.com) under "Links in the News."