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Nevins Retracts Key Paper By Duke Group, Raising Question Of Harm To Patients

By Paul Goldberg

Duke genomic researcher Joseph Nevins has notified his co-authors that he is retracting a paper that provides the scientific justification for two controversial clinical trials conducted at the university.

In an Oct. 22 email, Nevins, a senior author on the paper published in the Oct. 1, 2007, issue of the Journal of Clinical Oncology, acknowledged that patients at Duke were being assigned to cancer therapy based on a biomarker test that he now realizes is inaccurate.

In an email to the 13 co-authors on the JCO paper, Nevins said that the test predicted that some patients would respond to therapy to which they were, in fact, resistant. Others were classified as resistant to therapy to which
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Guest Editorial:

Retraction Based On Data Given To Duke Last November, But Apparently Disregarded

By Keith Baggerly and Kevin Coombes

The authors are biostatisticians at M.D. Anderson Cancer Center.

Given the lack of reproducibility, we agree that retraction of the 2007 JCO paper by Hsu et al. is appropriate.

However, this situation raises larger questions.

How did work with such flaws become the basis for clinical trials? The rationale for retraction implies that during the period from 2007 until now, when the signatures from this paper were being used in clinical trials, neither the investigators nor Duke University knew whether the signatures were valid.

Further, in November 2009, we identified and reported the exact problems now cited for retracting the paper. Details of our interactions with Duke are provided below.

Given that Duke knew of these problems in November 2009, why were these clinical trials reopened in January 2010?

Most importantly, how can we prevent these kinds of problems from happening again?

One characteristic of high-dimensional predictive “signatures” is that we have little intuition about what “makes sense.” We have to trust that the underlying analyses are correct, or at least checkable.

Before a new drug is introduced, specific tests have to be performed
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“Regrettably,” External Review Failed To See Flaws In Data

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they could be sensitive.

The journal is conducting an investigation prompted by the revelations that Nevins’ collaborator Anil Potti had misrepresented his credentials, falsely claiming, among other things, to have been a Rhodes scholar.

The email to co-authors is remarkable because a year ago Nevins, Potti and Duke administration officials had been given and apparently chose to disregard the same data that are now being cited as justification for the retraction, said Keith Baggerly, a biostatistician at M.D. Anderson Cancer Center, who attempted to validate the Nevins and Potti data and ended up auditing it. Baggerly said JCO had requested and received the information this September.

“In November 2009, we identified and reported the exact problems now cited for retracting the paper,” Baggerly and collaborator Kevin Coombes wrote in a guest editorial that appears on page 1 of this issue of The Cancer Letter. “Given that Duke knew of these problems in November 2009, why were these clinical trials reopened in January 2010?”

Duke officials acknowledge that a group of outside experts had reviewed the same data earlier this year, when the trials were briefly suspended in response to a Baggerly and Coombes paper pointing to the plausibility of harm. “Regrettably,” these outside experts failed to

detect a problem and recommended that the studies be resumed, a Duke spokesman said.

The email to co-authors signals an about-face for Nevins, who supported his collaborator Potti through four years of controversy over reliability of their findings. More importantly, Nevins has, in effect, admitted to the co-authors something that he and Duke officials had vehemently denied to the public: that patients may have been harmed in the course of the clinical trials of his group’s technology.

In the email, which was obtained by The Cancer Letter, Nevins wrote that in a database that was designed to predict the patients’ response to cisplatin, many tumors were improperly identified, leading to “reversal of the clinical annotation of response vs. non-response.

“As a result, predictions with the cisplatin signature cannot show a capacity to distinguish responders and non-responders when the correct clinical information was used, contrary to what was reported in the paper,” wrote Nevins, the Barbara Levine Professor of Breast Cancer Genomics and director of the Duke Center for Applied Genomics & Technology. “Given this, I believe that the paper must be retracted.”

This indicates that patients may have been harmed, experts say.

“If the trial was designed to assign patients based upon a faulty gene signature, then it’s safe to assume that patients might have been assigned to treatments that were unlikely to benefit them and possibly even to harm them,” said George Sledge, the Ballve-Lantero Professor of Oncology and professor of pathology and laboratory medicine at the Indiana University Simon Cancer Center and president of the American Society of Clinical Oncology. Though ASCO publishes JCO, Sledge is not involved in the journal’s investigation of the Duke team.

A bad biomarker can do more harm than a drug, experts say.

“You can do more harm by selecting therapies with a bad biomarker than by giving a proven drug to everyone, because with a biomarker you may be withholding an effective therapy from some people or giving an ineffective targeted drug suggested by your biomarker,” said David Carbone, the Harold L. Moses Chair in Cancer Research at Vanderbilt-Ingram Cancer Center and director of the Specialized Program of Research Excellence in Lung Cancer. “Thus, there is the possibility of patient harm when you apply an invalid biomarker to choose therapies.”

John Ruckdeschel, director and CEO of Nevada



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Cancer Institute and the Murren Family Distinguished Director's Chair, also noted the possibility of harm.

"All of us in the field of lung cancer were very excited about the possibility of having a panel of genetic markers that could, in general, distinguish the various forms of lung cancer with respect to their likelihood of response to therapy," said Ruckdeschel, a lung cancer expert. "Having markers that could specifically predict response to individual drugs was a further benefit of this type of research.

"It is disconcerting that these data, which have now been in existence for several years, turn out not to have been accurate. Certainly, the potential for patients to have been treated differently than they might have otherwise been is present and will need to be reviewed."

The plausibility of harm to patients in the Duke studies was first noted by Baggerly and Coombes, who devoted at least 1,500 hours to fact-checking the Duke team's claim that microarray analysis of patients' tumors can predict their response to chemotherapy. They found a multitude of instances where things didn't add up.

"Unfortunately, poor documentation can shift from an inconvenience to an active danger when it obscures not just methods but errors," Baggerly and Coombes wrote in a paper in the *Annals of Applied Statistics* in September 2009. "Patients in clinical trials are currently being allocated to treatment arms based on these results. However, we show in five case studies that the results incorporate several simple errors that may be putting patients at risk" (*The Cancer Letter*, Oct. 2, 2009).

The two studies in question had the combined enrollment of 71. A third Duke biomarker study, which has also been stopped, had the enrollment of 38.

Doug Stokke, a Duke spokesman, said the university doesn't believe patients were harmed.

"Because the arms in the impacted trials that were based on this work were primarily comprised of widely used, widely studied, or in some cases standard of care, regimens, we do not believe that patients were endangered through their participation in these studies," Stokke said in an email. "The study Data and Safety Monitoring Boards will be notified of this request for retraction." The studies were stopped after the controversy over Potti's credentials started in July.

The full text of the Nevins email follows:

"I write to you as a coauthor on a 2007 publication in *JCO* entitled 'Pharmacogenomic Strategies Provide a Rational Approach to the Treatment of Cisplatin-Resistant Patients With Advanced Cancer.'

"Two analyses provided evidence for validation of cisplatin predictor in this paper. One was a set of

ovarian cancer cell lines for which there were measures of cisplatin sensitivity, and the second was a dataset of 59 ovarian tumor samples for which there was clinical response data with platinum treatment.

"It is now clear to me upon re-evaluation of the data associated with the tumor samples that there are two problems with this dataset. First, there are 16 samples that do not match with the gene expression data from any of the ovarian samples that we have in our database.

"At this point, I cannot identify the origin or nature of these samples. It is possible they are from a set of non-ovarian samples or it is possible that they are ovarian samples that are permuted in a way that I cannot trace.

"But given that I cannot identify the nature of these samples, the associated clinical outcome labels are of no meaning. Second, for the remaining 43 samples that are clearly from the ovarian database, the tumor ID labels for these samples are incorrect. In a large number of these cases, the misidentification results in reversal of the clinical annotation of response vs. non-response.

"As a result, predictions with the cisplatin signature cannot show a capacity to distinguish responders and non-responders when the correct clinical information was used, contrary to what was reported in the paper.

"Given this, I believe that the paper must be retracted."

Who Knew What When

The Nevins email to coauthors now raises questions about what the Duke administration knew—and what it failed to acknowledge—about the scientific underpinnings of the three single-institution studies, two of which were based on the *JCO* paper that is now being retracted.

Enrollment in the three trials was first suspended last October in response to a Baggerly and Coombes paper (*The Cancer Letter*, Oct. 9, 2009).

In the course of subsequent investigation by Duke, Baggerly and Coombes provided the university with all the information now cited in the Nevins email to co-authors. However, at the time, Duke officials, the IRB, and experts hired by the university apparently disregarded the data and recommended restarting the three studies (*The Cancer Letter*, Jan. 29).

Duke spokesman Stokke said that the outside experts had reviewed the data that are now cited as justification for retracting the paper.

"Regrettably, the data sets that are the source of the retraction request are a subset of the same data that were provided by Drs. Potti and Nevins to external

reviewers in early 2010 and were the basis for their review,” Stokke said.

The university was secretive in its handling of the investigation. The names of experts who were asked to review the foundations of the three trials were never released, and their report, which supported restarting the trials, was intended to be kept under wraps.

However, a copy of the document was shared with NCI, where it became subject to the provisions of the Freedom of Information Act and was obtained by The Cancer Letter. Though heavily redacted by Duke, the document made it clear that the scope of the examination didn’t amount to validation of the work in question. Also, the document made it clear that Duke administrators were inaccurate in their initial public statement characterizing the report’s substance and conclusions (The Cancer Letter, May 14).

The three Duke studies continued through July, and were suspended only after The Cancer Letter reported that Potti had misrepresented his credentials (The Cancer Letter, July 16).

Since the suspension, an investigation by Duke University officials found “issues of substantial concern” in the credentials of scientist Anil Potti, and has imposed sanctions against him. A separate investigation by Duke is once again scrutinizing his scientific work.

Stokke said the decision to retract the paper “was made apart and separate from the scientific misconduct investigation that involves Dr. Potti.”

The university’s scientific misconduct investigation continues, Stokke said. “However, all of the information related to this retraction will be made available to the scientific misconduct investigation, and the NCI and the IOM committee that was recently formed to address the serious questions regarding this work have been notified of the retraction request and our concerns,” Stokke said.

The decision to retract the paper was based on recent analysis of the data. “The authors have been unable to reproduce the experiments using the original data sets,” Stokke said. “Therefore, the data in the paper don’t support the conclusions that were reported.”

The action by Nevins appears to dovetail with JCO’s investigation. Baggerly and Coombes gave the data to Duke last November, then posted the same information on their website in January.

They were also contacted by JCO in the course of the journal’s investigation, and they sent the data to the editor. A JCO spokesman said the journal hasn’t been notified about the intent to retract the paper and is continuing with its investigation.

NCI Director Harold Varmus has asked the Institute of Medicine, a body that usually focuses on broad science policy issues, to examine the Duke affair. That investigation will begin next year.

Asked to explain how the Duke team came to accept the Baggerly and Coombes data, Stokke said, “We can’t speak for Dr. Nevins and his team who analyzed the data and came to the conclusion regarding the need to request a retraction.”

Nevins didn’t respond to an email from The Cancer Letter.

PubMed lists 105 entries for Anil Potti. These include publications in some of the most prestigious medical journals.

The Lancet Oncology issued an expression of concern about a paper that sought to validate the work of the Duke scientists.

The scientific underpinnings of another paper, published in the Aug. 10, 2006, issue of the New England Journal of Medicine, appear to be similarly vulnerable. NCI and Cancer and Leukemia Group B eliminated the use of that biomarker from an ongoing phase III clinical trial (CALGB 30506) after failing to confirm the test’s utility (The Cancer Letter, May 14). The test wasn’t used to assign patients to treatment.

Also, another scientist has alleged that Potti had inappropriately obtained materials and manipulated the data that led to the NEJM paper (The Cancer Letter, July 30).

NEJM officials said they are relying on Duke to conduct an investigation.

Guest Editorial:

Statisticians Provide Timeline Of What Duke Knew When

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and clear documentation provided to FDA.

Before a signature we can’t intuitively grasp is introduced, we contend that the data and code used to generate the signature should be assembled with sufficient clarity for an independent group to easily run the code and confirm the predictions.

Before clinical trials using such a signature are begun, an independent group should run the code and confirm the predictions in a “reproducibility review.”

While we have recommended similar clarity to improve the reproducibility of results in the scientific literature (Baggerly *et al.*, Nature 2010), these recommendations become requirements before patients are treated. Such requirements could have precluded

the Duke trials from being started in 2007, restarted in 2010, and lobbied for without justification.

Empirically, pointing to publications without such reproduction is inadequate.

Of course, the devil is in the details. For this reason, we strongly support the IOM's "Review of Omics-Based Tests for Predicting Patient Outcomes in Clinical Trials." Part of the charge to that committee is to "recommend an evaluation process for determining when predictive tests based on omics technologies are fit for use as a basis for clinical trial design."

We suggest that a reproducibility review along the lines outlined above should be one of the criteria for evaluation.

A further part of the committee's charge is to "apply these evaluation criteria to predictive tests used in three cancer clinical trials conducted by Duke University investigators."

Part of this charge is now altered in focus.

Both Duke studies NCT00509366 and NCT545948 use the cisplatin and pemetrexed signatures. These should be terminated now. Given that test sample labels and outcomes have likewise been shown to be wrong for doxorubicin (repeatedly; see Case Study 1 in the *Annals of Applied Statistics* paper noted above), and NCT00636441 uses the doxorubicin signature, this should be checked immediately.

Thus, the focus shifts from "should these trials be allowed to continue?" (the answer is no) to "what simple steps would have prevented them from being started in the first place?"

In this context, it would also seem fruitful to examine both CALGB 30506 (the LMS trial), where David Beer has recently noted that test sample outcomes were mislabeled (*The Cancer Letter*, July 30, 2010) and CALGB 30702 (where expanded use of the cisplatin and pemetrexed signatures was proposed).

As we noted in our correspondence to *Nature*, "The quality of scientific output will benefit from setting these standards. As a community, we owe it to patients and to the public to do what we can to ensure the validity of the research we publish."

Here are the details of our interactions regarding the cisplatin and pemetrexed signatures:

By September 2009, when our paper raising the question of patient harm was published, at least one Duke clinical trial (NCT00509366) involving the cisplatin and pemetrexed signatures had been underway for two years. Another cooperative group trial using these signatures (CALGB 30702) had been proposed.

We identified the specific problems Nevins cites

for retracting the Hsu *et al.* paper in the *Journal of Clinical Oncology* (mislabeling of 43 of 59 ovarian validation samples, and scrambling of the array profiles for the other 16) in November 2009.

We reported these problems to Duke and to the NCI at the time (on Nov. 9 and 10, respectively). Duke had just suspended three clinical trials using genomic signatures (NCT00509366, NCT00545948, and NCT00636441) in October, including the one mentioned above, based on different problems we had identified and published in September (*The Cancer Letter*, Oct. 2, 9, 26, 2009, *Ann App Statist*, 3:1309-34, 2009).

At that time, Michael Cuffe, vice dean of medical affairs at the Duke University School of Medicine, said that "in light of the specific issues raised [in the *Annals* paper] about the application of this work to studies involving patients, we believe that pausing to re-confirm the scientific underpinnings of this work is in the best interest of the science ... We are working to engage independent experts in this field to fully explore these questions" (*The Cancer Letter*, Oct 9, 2009).

In January, Duke announced it was restarting the trials, stating that its investigation's results "strengthen ... confidence in this evolving approach to personalized cancer treatment."

We asked to see the raw data and the report justifying the trial restarts, citing, in part, the problems we identified and reported in November that remained (in our view) unresolved. The data and report were withheld. We then reported the problems publicly, posting full details on our website (*The Cancer Letter*, Jan 26, <http://bioinformatics.mdanderson.org/Supplements/ReproRsch-All/Modified/index.html>).

In May, *The Cancer Letter* obtained a redacted copy of the Duke internal investigation report from the NCI under the Freedom of Information Act. The report made no mention of the problems with cisplatin and pemetrexed that we had reported to Duke in November.

Based on their analyses of related data, the NCI and CALGB stopped tracking another genomic signature proposed by the Duke group, the lung metagene score (LMS), in the middle of a phase III clinical trial (CALGB 30506), stating that "they were unable to confirm the score's utility" (*The Cancer Letter*, May 14).

However, Duke continued to run the three previously suspended trials using genomic signatures, which the NCI had not funded and did not directly control.

Only in July, after "issues of substantial concern" were found with the CV of one of the principal

investigators and a letter from many in the biostatistics and bioinformatics communities to Harold Varmus, the newly-appointed head of the NCI, did Duke re-suspend the trials (The Cancer Letter, July 16, 23, and 30).

Also in July, JCO announced it was launching an investigation of the Hsu et al. paper. We have been corresponding with JCO about this issue since September.

Even before the errors noted were identified in November 2009, we had reported other severe errors involving these signatures: first to JCO in November 2007, and later, to Nature Medicine in May of 2008. Nature Medicine forwarded these problems to Potti and Nevins in June of 2008. We learned that clinical trials were underway in May/June of 2009.

Capitol Hill: **Grassley Seeks NCI Data On Sponsored Travel**

By Kirsten Boyd Goldberg

Sen. Charles Grassley (R-Iowa), ranking member of the Senate Committee on Finance, who has often called NIH to task over issues of ethics and conflicts of interest, is now focusing on “sponsored travel” of NIH employees to conferences, paid for by outside organizations or companies.

In a letter dated Oct. 22 to NIH Director Francis Collins and NCI Director Harold Varmus, Grassley raises questions about the amount of sponsored travel taken by “numerous NCI employees” in recent years.

“Each year, as a result of NCI’s policies, NCI employees appear to be spending many weeks and hundreds of thousands of dollars traveling to meetings and conferences,” the letter states. “For example, it has been reported to me that in 2008 and 2009, numerous NCI employees took between 10 and 20 sponsored travel trips. Many of the trips cost in excess of \$10,000, and some trips cost over \$17,000. In addition, the destinations were almost exclusively international, to countries like Germany, France, Italy, Switzerland, Japan, China and Brazil, just to name a few.”

The letter didn’t state who paid for the trips. Government employees can accept travel funds from non-federal entities for travel to meetings related to their jobs, but this requires several levels of approval and scrutiny, with reporting to the Office of Government Ethics.

In the letter, Grassley requests data from NCI on every sponsored travel trip approved in 2008, 2009 and

2010 for a list of 16 employees. He also seeks data on all official government travel in 2008, 2009 and 2010 for those employees.

The letter also asks for:

- The total value of all sponsored travel by NCI employees in 2008, 2009 and 2010.
- The total expenditure for all government paid travel by NCI employees in 2008, 2009 and 2010.
- The amount of NCI’s appropriation for government paid travel in 2008, 2009 and 2010.

Grassley also wrote that he is concerned that the former director of the NCI Office of Ethics was disciplined by NCI’s acting executive officer and transferred out of the institute. The senator’s staff later corrected that statement saying that the employee was transferred within NCI, accord to a report in Nature.

“We are putting together our responses and doing a thorough review, and will certainly respond to all of the senator’s questions and concerns,” NIH spokesman John Burklow said.

NCI has four levels of review for sponsored travel, including ethics review, Burklow said. An initial analysis appears to show that the travel is being sponsored primarily by universities and professional societies that invite NCI scientists to participate in scientific meetings and conferences.

Being invited to present one’s research is considered an important indicator of the value of the work, and counts highly in reviews, Burklow noted. Sponsored travel is only allowed for NIH employees working in the intramural research areas. Employees whose work focuses on the extramural research grant funding and oversight are generally excluded from taking sponsored travel as a matter of policy, he said.

“This is one important way science advances,” Burklow said. “Our scientists go out and share their work with others. The destinations sound attractive, but they go where the meetings are held.”

The scientists don’t receive honoraria for their appearances, Burklow said.

Grassley’s letter is posted at: <http://cancerletter.com/categories/documents>.

CORRECTION:

A story on the NCCN guideline that continues to include the use of Avastin for metastatic breast cancer (The Cancer Letter, Oct. 22), stated incorrectly that “there are no known phase III data on Avastin.” The sentence should have read. “there are no known new phase III data on Avastin.”

Letter to the Editor:
**IOM Study A Much-Needed
Step For “Omic” Research**

To the Editor:

The study of ‘omics’ is a laudable and much-needed step on the part of the IOM (The Cancer Letter, Oct. 22). I hope the committee chooses to include open verification of computational results in its proposed implementation of analytical validation.

The majority of published computational research today has not been reproduced nor independently verified--in part because this is essentially impossible without access to the underlying data and code.

Particularly when such research is to be the basis for clinical trials, it is important for the underlying methodologies that produced the results to be made openly available in sufficient detail to permit replication of the results. The consequences of not doing so can be dire, as we have just seen with the attempts to replicate the published computational results that engendered the now-suspended cancer clinical trials at Duke University.

What is needed is the establishment of open repositories for associated data and code (if these repositories do not already exist) and version labeling that ties together specific instances of code, data, and results.

This extra step of repository creation will permit the evaluation of the committee’s recommended criteria for predictive models intended to form the basis for clinical trials, as well as the dissemination of the methodologies and data required for verification of the published results by the community.

Victoria Stodden
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In the Cancer Centers:
**North Carolina Universities
To Foster Partnerships**

NORTH CAROLINA Central University and the University of North Carolina at Chapel Hill and its UNC Lineberger Comprehensive Cancer Center were awarded an \$11.9-million, five-year NCI grant to fund faculty partnerships between these two institutions to jointly develop programs, enhance training and support five research projects in prevention, screening, epidemiology

and the causation of cancer.

The Comprehensive Minority Institution Cancer Center Partnership Grant will bring more than \$7 million over five years to NCCU’s Julius L. Chambers Biomedical/Biotechnology Research Institute. UNC Lineberger will receive almost \$4.9 million. The NCI program is designed to foster intensive collaborations between minority-serving institutions and NCI-designated cancer centers to further develop approaches to understand and change the significant disparities in cancer outcomes observed in minority and socio-economically disadvantaged populations.

Led by **Ricardo Richardson**, director of the cancer program at the BBRI, and **Shelton Earp**, UNC Lineberger director, the grant will initiate a joint program to increase the number of undergraduate students from both universities pursuing careers devoted to causes and prevention of minority disparities. The grant will also help fund new junior faculty hires at NCCU to build cancer research capacity.

CITY OF HOPE researchers have been awarded \$6.3 million by the California Institute for Regenerative Medicine for research and development of stem cell-based therapies to treat HIV/AIDS, Parkinson’s disease and Canavan disease, an often fatal neurological disease that affects infants. The organization has previously received more than \$36.7 million in grant support from CIRM.

David DiGiusto, professor in City of Hope’s Department of Cancer Immunotherapeutics and Tumor Immunology, is leading the development of a new gene-therapy for HIV infection. **Larry Couture**, senior vice president of the Sylvia R. & Isador A. Deutch Center for Applied Technology Development, is collaborating with the Buck Institute for Age Research in Novato, Calif., on developing a treatment for Parkinson’s disease. **Yanghong Shi**, associate professor in the Department of Neurosciences, is leading a collaboration with the University of Bonn in Germany into Canavan disease, which has no standard course of treatment.

EMORY UNIVERSITY and the Georgia Institute of Technology researchers will collaborate on work in head and neck cancers and pancreatic cancer using two grants from the NCI’s Cancer Nanotechnology Platform Partnerships program. The cooperative five-year grants totaling \$4.7 million will be used to develop nanoparticles as diagnostic and therapeutic tools against cancers.

The first grant totals more than \$2.3 million over

five years and is awarded to **Dong Moon Shin**, professor of hematology, medical oncology and otolaryngology and director of the Winship Cancer Chemoprevention program, and **Mostafa El-Sayed**, Regents professor of chemistry and biochemistry and director of the Laser Dynamics Laboratory at Georgia Institute of Technology.

The second NCI grant for nearly \$2.4 million over five years was awarded to **Lily Yang**, associate professor of surgery, and **Hui Mao**, associate professor of radiology and Center for Systems Imaging, both at Emory.

UNIVERSITY OF WISCONSIN-MADISON assistant professor of oncology **Wei Xu** received a 2010 Era of Hope Scholar Award from the U.S. Department of Defense Breast Cancer Research Program. Based at the McArdle Laboratory for Cancer Research and a member of the UW Carbone Cancer Center, Xu will use the \$3.6 million grant over five years to further her studies on estrogen receptors. Xu has identified two naturally occurring compounds that selectively activate ER-beta. In one aim of the planned studies, she and her colleagues will evaluate the properties of these compounds to determine if they might prove effective in treating breast cancer.

MAYO CLINIC has implemented a front-line system of technology for electronic data capture and management, according to **Gloria Petersen**, associate dean for research informatics. The Clinical Trials Management System will eliminate duplication, delays and errors caused by manual data entry, Petersen said.

“When combined with Mayo Clinic’s impressive array of clinical laboratory services and outstanding clinician-investigators, this new CTMS makes Mayo an ideal coordinating site for drug and device trials and large clinical research studies of all kinds,” Petersen said.

“With support from the National Cancer Institute, Mayo’s CTMS will be using an enterprise-wide clinical data management system—Medidata Rave—to manage large, complex or multi-site clinical research studies,” said **Daniel Sargent**, Mayo Clinic biostatistician and chair of Mayo’s CTMS Oversight Committee. “While NCI is providing access to this data management system to NCI-supported not-for-profit organizations that conduct clinical research in the field of cancer, Mayo is taking it a step further by making our CTMS available to all researchers at Mayo, including both cancer and non-cancer studies.”

UCLA JONSSON Comprehensive Cancer Center researchers received a \$14 million grant to develop countermeasures that will help treat damage caused by radiological or nuclear threats such as a dirty bomb attack.

The grant, awarded by the National Institute of Allergy and Infectious Diseases, is a renewal of a five-year \$14 million grant first awarded to UCLA in 2005. The grant is part of a major research effort to develop medical products to diagnose, prevent and treat the short- and long-term consequences of radiation exposure after a radiological or nuclear terrorist attack.

William McBride, a professor of radiation oncology and a Jonsson Cancer Center researcher, serves as UCLA’s principal investigator.

HOLLINGS CANCER Center at the Medical University of South Carolina researchers have won a \$1.4 million grant from the Department of Defense to enhance breast cancer research at MUSC.

The four-year grant, which partners Hollings researchers with a team from the Baylor College of Medicine, establishes a breast cancer research training program at MUSC called BRIDGE, or Breast Cancer Research Initiative for Developing Growth and Education. The program is designed to enable young investigators from MUSC to be closely mentored by scientists from MUSC and Baylor College of Medicine.

Carola Neumann, assistant professor of cell and molecular pharmacology at MUSC, and **Kent Osborne**, professor of medicine and director of the Breast Cancer Program at Baylor, will lead the teams.

THOMAS GEORGE JR., a University of Florida assistant professor of hematology and oncology, was recently tapped by **Gov. Charles Crist** to serve as chairman of the Florida Cancer Control and Research Advisory Council.

George, a member of the UF Shands Cancer Center and the director of the UF gastrointestinal oncology program, has been a member of the 35-member council since 2006, and will serve as the council’s chairman for a term of four years.

The council is charged with advising Florida’s governor, Legislature, surgeon general and other state agencies on cancer control issues, preparing position statements on cancer-related legislation and assisting in the development and funding of projects aimed at reducing the cancer burden in the state, especially among low-income and underserved populations.