

# ACRIN NEWSLETTER

Advancing Clinical Care Through Imaging Research

American College of Radiology Imaging Network

June 2006



## ACRIN CHAIR'S COLUMN

*Bruce J. Hillman, MD*

This issue's column is about money. That subject usually causes ears to perk up—and well it should. ACRIN's mission of improving the length and quality of life of cancer patients depends on a continuing flow and the expansion of funding. However, as we all know, the days of increasing NCI budgets are over. For the past two years, the NCI budget has been flat. Given inflation and the development of several new, large NCI priorities, there are fewer moneys available for continuing programs such as ACRIN. We were recently notified of an across-the-board cut in such programs of 2.35%, which we must absorb in our 2006 budget.

This comes at a bad time for ACRIN. We are writing an application to renew ACRIN's core funding this year. There is an ever-expanding list of excellent scientific opportunities being generated by our ACRIN Scientific Committees. Our Philadelphia Office infrastructure is just rebounding from the financial stringency of the past several years. Finally, the interest in and support of imaging at NCI has never been greater. There has been great enthusiasm among NCI leadership for what ACRIN already has managed to accomplish. As the newest of the clinical trials cooperative groups, we have a much greater potential for growth than many others.

We need to seize the opportunity, but how do we do so given the current federal funding climate? Over the past year, ACRIN leadership has been working to develop new sources of revenue to supplement our group's core NCI funding. One specific initiative has been the ACRIN Fund for Imaging Innovation, a philanthropic campaign greatly aided by the American College of Radiology (ACR). The ACRIN Fund will be headed by a Board which will work with ACRIN leadership to determine how the Fund moneys will be deployed. The moneys derived from the ACRIN Fund will allow more flexibility than we have had in the past: a stabilized infrastructure, more trials, and enhanced investigation of issues such as quality of life and the cost of care.

The ACR donated \$1 million to kick off the campaign and promised a matching gift of another \$1 million once the campaign achieved an additional \$5 million from other sources. The ACRIN Fund has accomplished that goal, raising just over that amount, largely from corporate gifts. Pledges to the ACRIN Fund now stand at more than \$7.2 million, and we are entering an expanded phase of solicitation that we hope will take us even higher.

I want to express my gratitude to those who have worked hard to make the campaign a success and provided important donations. We recognized early on that the only way the campaign could be successful was to have outstanding leadership. As Campaign Chair, Tom McCausland, President and CEO of Siemens Medical Solutions USA, has been the driving force who has ensured that we would achieve our goal. He has spearheaded a leadership cabinet of outstanding industrial leaders and physicians and called upon his own contacts in the corporate world to make sizable donations. In addition, the ACR Board of Chancellors and Council Steering Committee have contributed over \$200,000.

Building on this success, we are now expanding the campaign to individuals who believe in the importance of ACRIN. Please consider making a donation to the ACRIN Fund to help ensure that our work continues.

## 2006 ACRIN Fall Meeting

Save the date:  
October 5 - 8

Ritz-Carlton, Pentagon City  
More details coming soon!

## ACRIN FUND FOR IMAGING INNOVATION

### Fund Update

The \$300,000 goal for individual and radiology practice contributions to the ACRIN Fund is within reach! Contributions as of June 12 total more than \$245,000 and more pledges are coming in daily. This brings the total to over \$7.2 million. Thank you to all who have contributed to support ACRIN's research.

If you are considering a pledge, there is still time. A pledge form is available on the ACRIN Web site's home page:  
[www.acrin.org](http://www.acrin.org).

### Message From a Recent Donor

"Hitachi Medical Systems proudly supports ACRIN. Its ongoing efforts to advance innovative diagnostic and therapeutic technologies will make a difference in improving the prognosis and quality of life for cancer patients."

### Don Broomfield

*President and CEO*

*Hitachi Medical Systems America, Inc.*

### ACRIN Fund Contributors

Corporate and individual donors are recognized on pages 5 and 6.

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## AN INTERVIEW WITH MITCH SCHNALL MD, PhD



*Mitchell Schnall, MD, PhD, of the University of Pennsylvania, currently serving as deputy chair of ACRIN, will become ACRIN network*

*chair in 2007. Dr. Schnall's research has focused on applying imaging-MRI in particular—to the detection and characterization of cancer. As ACRIN begins to prepare its new grant application, Dr. Schnall discusses the history and future of the organization.*

### How did you become involved with ACRIN?

I was involved in ACR trials, including the breast MRI consortium, which was in some ways the predecessor of ACRIN. When Bruce Hillman was putting together a team to start ACRIN, he asked me to join and become the deputy chair of the Network.

### Have you worked on specific ACRIN trials?

I haven't participated in the trials as a researcher, but I think that our trials are a great way for younger faculty to learn about research. We've had a broad involvement in ACRIN trials here at Penn. ACRIN provides junior faculty with cross-institutional mentoring and an opportunity to learn about rigorous clinical research.

### What is the process of developing the new grant?

It's not an easy process. We receive input from the scientific committees and from ACRIN administration to find out how people view their organization. We're starting to disseminate templates now, and then the different groups all write their parts. After that, we refine the pieces and stitch them all together. Although we go through this process to put together a document to submit to NCI, the process also helps us as an organization come together to focus ourselves. We're all working towards a common goal.

### How will the research objectives guide ACRIN's work?

These objectives aren't new; they have grown from our objectives in the past.

As we've watched what's going on in cancer care, we've refined and defined our objectives a little more clearly. We need to understand that cancer is a disease that comes in many forms and shapes even in a particular organ system, and we need to start taking a personalized approach to diagnosis and treatment.

### In what direction do you hope to see ACRIN move over the next several years?

I'd like to see ACRIN expand and focus on its scientific mission, but I'd also like to see it become more active in developing collaborative relationships with cooperative groups and other researchers. I would like to see us continue to establish standards for imaging quantification.

### What is the biggest challenge facing ACRIN right now?

The biggest challenge is maintaining the passion of our investigators. We've established a broad network, with many participants in both leadership and site positions. ACRIN is an organization that has to have broad reach and input—it can't be driven from the top. The success of this organization depends on everyone involved helping to move it forward.

## ACRIN OBJECTIVES: SHAPING OUR FUTURE RESEARCH

Biomedical imaging now offers the opportunity to characterize tumor anatomy, physiology, and molecular biology in unprecedented ways. These objectives, written as part of the new grant application, will help ACRIN harness this technology and develop quantitative approaches to diagnosis and broadly conceived image guided therapy that will support the development and application of targeted treatments and preventive interventions.

1. Develop appropriate and effective strategies for implementing imaging in the surveillance of populations at high risk for cancer.
2. Establish imaging approaches to the characterization of disease anatomy, physiology, and molecular biology in order to guide the administration of targeted therapies.
3. Identify, standardize, and validate biomarkers of therapeutic response for implementation in clinical trials and clinical care of cancer patients.

The ACRIN Newsletter is published by ACRIN Headquarters and distributed to participants and others interested in the Network.

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## NATIONAL ONCOLOGIC PET REGISTRY HELPS HUNDREDS OF PATIENTS IN OPENING WEEKS

Thanks to the May 8 launch of the National Oncologic PET Registry (NOPR), Medicare beneficiaries now have PET scan coverage for nearly all types of cancers. As of May 25—less than three weeks after the NOPR's opening—more than 800 people had received PET scans covered by Medicare through the NOPR program. Also, more than 1000 PET facilities nationwide had registered to take part in the NOPR and can now be reimbursed by CMS for PET indications previously not covered.

"In its opening weeks, this landmark project has already provided lifesaving technology to those for whom it was previously out of reach," says Barry Siegel, MD, FACP, ACRIN researcher and co-chairman of the NOPR Working Group. "Many patients' only choice, prior to the NOPR, was to pay for these exams out of pocket. That was not realistic for most. I am proud that CMS, in collaboration with the leadership of key research organizations, found a way to make this care available to those who desperately need it."

The NOPR, managed by the ACR and ACRIN, will collect data to assess the impact of PET in the management of patients with various forms of cancer or suspected cancer. NOPR investigators, with data analysis support from the ACRIN Biostatistics Center at Brown University, will report their findings to CMS.

Ovarian cancer survivor Laurel Pracht (see sidebar) had a PET scan May 9, the day after the NOPR was launched. "It's heartening to be able to go into a PET center and not worry about the money," she says. "As a patient who continues to rely on information provided by PET, I'm convinced that the NOPR project will benefit thousands of Medicare patients nationwide who may have little time or money to spare."

## "SCIENTIST TO SURVIVOR" PROGRAM: A PARTICIPANT'S VIEW

by *Barbara LeStage, ACRIN Patient Advocacy Committee Chair*



Peggy Devine, Vice Chair of the ACRIN Patient Advocacy Committee, and I were fortunate to be two of 36 advocates selected from six countries to attend "Scientist to Survivor," a program offered as part of the annual meeting of the American Association for Cancer Research (AACR).

This five-day program builds bridges between the leaders of the scientific and cancer advocacy communities. The program helps advocates develop stronger backgrounds in cancer research; keep up with recent advances in basic, clinical, and translational cancer research; communicate their key issues, questions, and concerns to scientists; promote their organization's mission; and network with other advocates.

Our busy days began with a 7 A.M. "Sunrise Session" and ended after an evening reception or awards dinner. We attended the regular AACR lectures, forums, symposia, and poster sessions. However, it was the presentations given just for

## ADVOCATE CHAMPIONS NOPR STARTUP



*Laurel Pracht  
Cervical Cancer Survivor  
and Advocate*

Laurel Pracht doesn't take no for an answer. A nearly seven-year ovarian cancer survivor, Pracht was happy when she

heard in January 2005 that Medicare would cover PET scans for ovarian cancer as part of the National Oncologic PET Registry; she had self-funded three PET scans when Medicare wouldn't pay for them. But when NOPR ran into regulatory issues at the Office of Human Research Protections (OHRP) this spring, the opening date became uncertain.

Pracht and the ACRIN advocates sprang into action. Pracht called people at the OHRP to explain what the NOPR meant to cancer patients. "I've known women who have died before paying off their PET scans," she says. "I thought the patient's voice was getting lost in all of this, and it needed to be heard. I've learned that patients must advocate for each other and for themselves." She was persistent, calling every day. She also contacted her representatives in Washington, DC. Thanks to input from patient advocates, NOPR researchers, institutional review board chairs, and policy makers, the regulatory issues were resolved, and the NOPR was launched May 8.

Pracht feels thankful to see the NOPR up and running. She says her experience has taught her that "the lone patient's voice can be heard." Her PET scan on May 9 showed no sign of recurrence.

*continued on page 4*

## ACRIN GAINS FDA EXPERIENCE

ACRIN clinical trials involving an investigational drug and device are expected to launch late summer or early fall (see trial descriptions below). These trials are a first for ACRIN, reports Maria Oh, ACRIN's director of protocol development and regulatory compliance. "It is the first time ACRIN will lead trials that involve an investigational contrast agent and device for which Food and Drug Administration approval is being sought," she says. "It has been a learning experience for our organization to address all of the related regulatory issues and an exciting opportunity for us to work with the NCI and the FDA to fulfill the trials' regulatory requirements. Given our new knowledge base, we hope ACRIN will have the opportunity to develop future trials involving investigational drugs and devices."

### ACRIN 6674/ InSightec BC005: Treatment and Its Evaluation with Focused Ultrasound Ablation under MRI Guidance (MRgFUS)

Principal Investigator: Mitchell Schnall, MD, PhD

Co-Principal Investigator: Christopher Comstock, MD

The goal of this trial is to evaluate both the effectiveness of Focused Ultrasound Ablation Under MR Guidance (MRgFUS) in destroying breast cancers and the sensitivity of post-treatment MRI in identifying residual disease following ablation. This trial is a collaborative effort with InSightec, a company that developed a device that performs non-invasive surgery through the combination of high intensity focused ultrasound and real time MRI based guidance and monitoring. This trial presents new regulatory requirements for ACRIN because it involves an investigational device. Investigators in this trial, which currently has a conditional approval from the Food and Drug Administration (FDA), will use InSightec's ExAblate system for the ablation of cancerous breast tissue. The procedure combines a focused ultrasound surgical system and a conventional diagnostic 1.5T or 3T MRI scanner.

### ACRIN 6671/GOG 0233: Treatment Planning with PET/CT and Contrast MRI

ACRIN Principal Investigator: Mostafa Atri, MD

GOG Study Chair: Michael Gold, MD

A collaboration between ACRIN and the Gynecologic Oncology Group (GOG), this clinical trial will study patients with locoregionally advanced cervical cancer and evaluate the diagnostic accuracy of both preoperative FDG-PET/CT imaging and preoperative MRI scanning using an investigational contrast agent Combidex (ferumoxtran-10) to identify pelvic and abdominal lymph node metastases. The protocol has been submitted to both the FDA and Cancer Therapy Evaluation Program (CTEP) for review and is awaiting final approvals.

The National Cancer Institute's Cancer Imaging Program is the Investigational New Drug (IND) holder for the Combidex FDA application process. Example MRI images using Combidex, a contrast agent with iron oxide nanoparticles, are shown below. Sites are now being recruited to participate. For information, visit [www.acrin.org/6671\\_protocol.html](http://www.acrin.org/6671_protocol.html).

**Figure 1. 65 year-old male with prostate cancer and nodal metastases, 24 hours post Combidex injection. Left iliac side.**

**A.** Semi-sagittal T1-weighted TSE MR image, insensitive for iron, shows node (arrows). Shape and size can be exactly determined.

**B.** T2\*-weighted GRE MR image in exactly same plane as (A), sensitive to iron, shows that this node is completely black and thus contains normal nodal tissue with iron loaded macrophages. Lymph node dissection confirmed normal non-metastatic node.

Courtesy of Jelle O. Barentsz, MD, University Medical Center Nijmegen, Netherlands.



*continued from page 3*

advocates I found the most helpful because they were geared to laypersons and provided an opportunity to ask many questions. Dr. Scott Lippman, for example, discussed the need to identify high risk populations that would benefit from chemoprevention and to determine which sub-populations of cancer patients will benefit from certain treatments. Dr. David Sidransky talked about emerging molecular technologies in prostate cancer detection and the need to collect and analyze molecular markers in all clinical trials.

In my role as ACRIN's PA Committee Chair, I found three lectures particularly interesting. Dr. Walter Wolf addressed the importance of using imaging to determine pharmacodynamic activity and the optimal therapeutic dose (versus the maximum tolerated dose) in Phase I/II trials. Dr. Michael Gee proposed using near-infrared fluorescence optical imaging to provide noninvasive assessment of treatment susceptibility, drug target inhibition, and early therapeutic response by attaching probes to monoclonal antibodies. Dr. Martin Pomper discussed single photon emission computed tomography (SPECT) and the fact that tumor size in determining response to therapy will become irrelevant in the future. From my lay perspective, these concepts may offer interesting possibilities for future ACRIN trials.

Although the small number of presentations about in vivo imaging was disappointing, my overall experience with the Scientist to Survivor program was outstanding. I was excited that the new proposed ACRIN clinical research objectives seem to have ACRIN positioned to lead the country in cutting-edge imaging research, and I look forward to participating in that endeavor.

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*The ACR donated \$1 million to kick off the campaign and promised a matching gift of another \$1 million once the campaign achieved an additional \$5 million from other sources. The ACRIN Fund has accomplished that goal, raising just over that amount, largely from corporate gifts.*

Bruce Hillman  
ACRIN Network Chair

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