

# ACRIN NEWSLETTER

Advancing Clinical Care Through Imaging Research

American College of Radiology Imaging Network

OCTOBER 2006



## ACRIN CHAIR'S COLUMN

*Bruce J. Hillman, MD*

We've come a long way, but there is still much to accomplish. With just over a year to go before I relinquish my chairmanship of ACRIN, I am feeling this particularly strongly. ACRIN has become a well-recognized and integral part of the NCI clinical trials portfolio and, more broadly, of the cancer research community. This has occurred thanks to the efforts of hundreds of individual researchers at academic institutions, community hospitals, and imaging centers, as well as the expertise of outstanding staff at the Philadelphia ACR Headquarters and Brown Statistical and Data Management Center.

Especially critical to our success has been the relationship between ACRIN leadership and the Cancer Imaging Program (CIP). The reason we are called a "cooperative group" is that--unlike investigator-initiated grants--the ACRIN grant is intended to be based on an extensive and continuing exchange between the researchers and CIP, our granting agency.

Beginning in October, CIP will celebrate its tenth anniversary. In that short time, CIP has succeeded well beyond the hopes many of us in radiology had for it. As a result, the national research establishment now holds medical imaging in much higher esteem than previously, and the NCI budget for imaging research has progressed extraordinarily. A handful of people are responsible, most importantly Dr. Dan Sullivan, who has headed CIP nearly from its inception. ACRIN, now nearly eight years old, has been among the primary beneficiaries of Dan's persuasive leadership of CIP. Much of ACRIN's success can be attributed to Dan's championing of our capabilities to NCI leadership. Just as important have been the efforts of several of his staff: Barbara Galen, MSN, CRNP, CNMT; Ed Staab, MD; and Carl Jaffe, MD. Barbara has been particularly tenacious in helping ACRIN achieve its goals by guiding ACRIN leadership through the various mazes of regulation and bureaucracy, ensuring that we were fully engaged with the appropriate budgetary and financial personnel, and helping us through the occasional difficult episode.

The CIP staff is now engaged in generating the renewal of fund application (RFA) that we hope and expect will lead to the renewal of ACRIN for another funding cycle beginning in January 2008. We expect to see that RFA later this year. Dr. Mitch Schnall, MD, the new Network Chair designee, will head the team that will respond by generating a lengthy proposal, organizing a site visit, and--we expect--leading ACRIN to continued successes.

Several of the therapeutic cooperative groups are currently marking their fiftieth year of performing clinical cancer research. ACRIN is just a toddler in comparison. Nonetheless, I truly believe that the foundation of collaboration we have set during our first eight years has prepared ACRIN for great things as we progress into the future.

## PROTOCOL UPDATE

The following four ACRIN protocols are scheduled to open in the next several months.

### **ACRIN 6671 Cervical Cancer: Treatment Planning with PET/CT and USPIO MRI**

Principal Investigators:  
Mostafa Atri, MD (ACRIN)  
Michael Gold, MD (GOG)  
ACRIN Project Manager:  
Bernadine Dunning  
(bdunning@phila.acr.org)

### **ACRIN 6674 Breast Cancer: Treatment and Treatment Evaluation with Focused Ultrasound Ablation under MRI guidance (MRgFUS)**

Principal Investigators:  
Mitch Schnall, MD, PhD  
Chris Comstock, MD  
ACRIN Project Manager:  
Bernadine Dunning  
(bdunning@phila.acr.org)

### **ACRIN 6675 Malignant Melanoma Metastases: Treatment Response Monitoring with FDG-PET**

Principal Investigators:  
Terrance Wong, MD, PhD (ACRIN)  
Kim Margolin, MD (SWOG)  
Project Manager:  
Donna Hartfeil (dhartfeil@phila.acr.org)

### **ACRIN 6676 Renal Cell Carcinoma: Predicting Treatment Response with DCE MRI**

Principal Investigators:  
Mark Rosen, MD (ACRIN)  
Keith T. Flaherty, MD (ECOG)  
Project Manager:  
Donna Hartfeil (dhartfeil@phila.acr.org)

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**RADIOLOGY**  
IMAGING NETWORK

## ACRIN'S GRANT RENEWAL PROCESS: A TEAM EFFORT

*Preparing the grant for ACRIN's next funding cycle requires a team of people to commit substantial time and energy in the preparation of a document that will greatly affect ACRIN's future research work. The following highlights ACRIN's grant history and the many people involved in the grant preparation.*

### *Why is the grant and corresponding application process important to ACRIN?*

Most of ACRIN's funding comes from the National Cancer Institute (NCI). The Renewal of Funds Application (RFA) gives ACRIN the opportunity to show that we have used our funds effectively and allows us to make the case for continued funding. It provides our organization an opportunity to clarify and refine our scientific objectives and set the course for future research.

### *What has been ACRIN's past NCI funding experience?*

In 1999, ACRIN received its first core grant, which provided \$23.2 million over 5 years to ACRIN Headquarters and the Biostatistics and Data Management Center. The initial funding was to establish an imaging network that could support multicenter imaging research trials. ACRIN made its first application for renewal of the grant for funds beginning in 2004, and the organization was funded for a renewal of \$20.3 million for four years, from 2004 to 2007.

From early in ACRIN's history, however, it was clear that the core grant would not provide sufficient funding for several large-scale imaging trials that sought to answer important research questions. The National

Lung Screening Trial (NLST) and the Digital Mammographic Imaging Screening Trial (DMIST), two screening studies of great scientific interest to both ACRIN and NCI, required supplemental funding. DMIST was given a supplemental grant of \$26.5 million, the NLST received \$115.5 million, and, more recently, the National CTC Colonography Trial was granted \$6.9 million. In addition, in 2004 ACRIN sought funds to supplement the core grant to fund its general research and received \$2 million a year for the next three years. With the new RFA, these general funds will be incorporated into the core grant.

ACRIN has also received funding from NCI's new Integration and Implementation (I2) grants. The I2 funding initiative helps develop imaging components for other cooperative group trials. Embracing this opportunity is part of ACRIN's growth as a service-side organization for other treatment groups, allowing us to provide them with our infrastructure and expertise.

### *What role does headquarters play in the grant renewal application?*

Philadelphia Headquarters staff coordinate the submission of the application; the last application was over 300 pages. Staff draft the grant components that detail ACRIN's infrastructure and daily operation, describing everything from the image submission processes to ACRIN's informatics resources. The grant also explains how various departments and committees work together towards ACRIN's scientific goals. After the application has been submitted, plans for a site visit will be coordinated.

Charles Apgar, MBA, Director of ACRIN Administration, says, "In

tight fiscal times, we don't have the luxury of having resources to do whatever we want. The grant application process allows us to focus our energies. With ACRIN researchers and staff working together, we can leverage the funds we have and move forward towards our goal of rigorous scientific research."

### *How does the ACRIN Biostatistics Data Management Center coordinate their grant submission with ACRIN Headquarters?*

The NCI requires the Biostatistics and Data Management Center (BDMC) to submit a separate grant in conjunction with the one submitted by ACRIN Headquarters. (Statistical analysis for ACRIN is provided by the Biostatistics Center at Brown University.) The two portions of the grant must be coordinated throughout the process to ensure they mesh. According to Constantine Gatsonis, PhD, Director of the Biostatistics Center at Brown University, "At every step of the application process, the BDMC and ACRIN Headquarters work closely to ensure that the proposals from both parts of the ACRIN organization fit together to further ACRIN's scientific objectives."

### *What role do the disease site committee chairs play?*

The chairs of the disease site committees (DSCs) work with their committee members throughout the year to shape ACRIN's research. Each DSC is responsible for writing the part of the grant that describes the committee's past activities and outlines plans for future research. During the site visit, the chair of each DSC demonstrates why the committee's work is scientifically rigorous and of importance to the cancer research community.

*Grant Renewal continued on page 6*

## THE ACRIN GRANT: A DISEASE SITE COMMITTEE CHAIR'S PERSPECTIVE



*Donald Mitchell, MD, chair of the ACRIN Gynecology Disease Site Committee, discusses his committee's work and explains how the committee is helping ACRIN prepare for the grant application.*

After the last grant cycle, all the disease site committees were asked to set priorities and come up with directions for research. For the new grant application, we were asked to

write a 7- to 10-page summary detailing our work over the past four years. In writing the summary for the grant, it was interesting to see the initial criticisms from NCI, and then see how we've addressed them and evolved.

The strengths of the Gynecology Committee are the diversity and background of the committee members. We have both imaging specialists and people outside imaging fields. One big source of additional committee members has been people we're collaborating with on trials, people who have invested time and effort in imaging research. A big part of what the committee does is work with other collaborative groups, such as GOG and RTOG. As a committee, we communicate through e-mails, conference calls, and meetings. We had a lot of discussions at the ACRIN Spring Meeting about the committee's

direction, and we will be meeting at the ACRIN Fall Meeting to lay the groundwork for the site visit.

Our research is progressing toward molecular imaging and translational research, beyond staging to more precise mapping and characterization of tumors. Imaging is becoming more and more integral to how medicine is practiced; imaging is becoming more and more precise, and so are treatments. Before, with staging, imaging would be used to detect a cancer and to assign patients to certain categories, and then treatment would be decided statistically according to a patient's category. Now we're moving more towards directly seeing and treating the tumor, while sparing other tissue. We can characterize the tumor better and very rapidly find out the response to treatment. This is an important new direction in imaging research.

## ACRIN FUND FOR IMAGING INNOVATION

Having raised over \$7.2 million for the ACRIN fund, thus far, the campaign phase of this successful endeavor formally concluded in September. However, opportunities will continue to be sought to raise additional funds for this important work. To coordinate future ACRIN Fund and other industry efforts, the ACR is taking the major step of hiring a corporate relations staff member who will serve as a link between the ACR and its industry partners. We look forward to introducing you to this person in the next newsletter. Meanwhile, Brad Short, Senior Director of ACR Member Services (800-227-5463 ext. 4975; [bshort@acr.org](mailto:bshort@acr.org)) can respond to questions.

*Look for the new display recognizing the ACRIN Fund's corporate and individual donors at the ACRIN Fall Meeting.*



*Robert Pryor, President, HealthCare America and Harvey Neiman, MD, ACR Executive Director, visited ACRIN headquarters recently to discuss strategic priorities for ACRIN, ACR, and AGFA and possible future collaborations.*



## ACRIN ADVOCATE HEADS MODALITY DESCRIPTION PROJECT

*ACRIN advocate Missy Layfield can pinpoint when her advocacy work began. She says, "I became a patient advocate the day my son was diagnosed with leukemia in 1995." Her advocacy for her son broadened into work with the Children's Oncology Group (COG) when she joined COG's patient advocacy committee in 2000. Missy credits her background as a physical therapist and athletic trainer with teaching her useful advocacy skills: "In those two fields, you're always walking into unique situations that*

*require self-education. I'm used to asking questions. I'm not ashamed to admit when I don't know something."*

ACRIN gave Missy plenty of opportunities to ask questions. When ACRIN was recruiting advocates in 2003, Missy's experience made her a natural choice, and she was eager to provide a voice for pediatric patients in imaging studies. "I had to learn practically everything about imaging, though," she says. "My imaging experience was limited. My son had had some imaging, but he was diagnosed with leukemia, scans weren't a huge part of his treatment. My learning curve was very steep at first." She began by working on ACRIN 6660, the pediatric malignancy protocol, and recently she has also started working on ACRIN 6671, a cervical cancer protocol.

Missy says that having to learn imaging from scratch put her in a good position to work on her latest project: creating standardized modality descriptions for ACRIN trials. As the advocates reviewed ACRIN's protocols and protocol concepts, they noticed that there was little consistency in the modality descriptions from protocol to protocol, especially in the informed consent forms and the recruitment literature. Missy led ACRIN advocates and researchers in creating template language that ACRIN investigators could draw on when creating protocols. "The advocates saw a need," she says, "and we thought this project would fit perfectly into what we were trying to do, which is to translate protocols into lay language for the study participants." She hopes that the descriptions will ultimately be useful not only to ACRIN researchers, but also to other cooperative groups as well.

Missy speaks glowingly of her work with ACRIN. "I have felt welcomed into the whole ACRIN family of researchers," she says. "The administration of ACRIN has been just wonderful about introducing us and helping us get the information we need. It's been quite a fulfilling experience."

## PERSONNEL UPDATE

Pamela Harvey recently joined ACRIN as the Director of Data Management. Pam holds a master's degree in management and brings over 27 years of varied experience in the research industry that includes work with contract research organizations and pharmaceutical and bio-tech companies. Most recently, she was a consultant for Novartis, Alteon, Pfizer, and Schering Plough. Pam mentions she enjoys managing teams to accomplish projects such as database design, study set up, forms design and query tracking, "It's a thrill when everyone works together and meets study timelines."

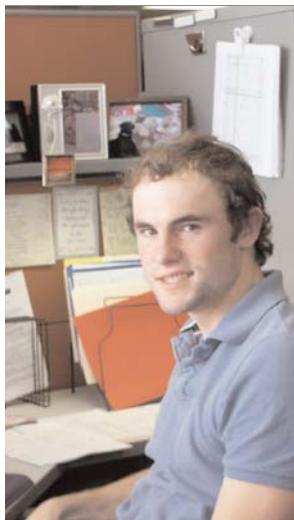
Sophia Sabina has assumed the position of Data Standards Administrator in which she can apply her extensive data management knowledge to lead projects related to standardizing data elements pertinent to medical imaging clinical trials. She is currently engaged in a National Cancer Institute project to develop CDE's (common data elements) for imaging cancer research. Sophia's involvement will allow ACRIN to be at the forefront of incorporating standard data elements and forms into research trials.

In other personnel changes, Nancy Fredericks was promoted to Assistant Director of Diagnostic Imaging. In addition to her communications and recruitment responsibilities, she will take the lead in operational activities.



*Pam Harvey, Director of Data Management, talks with Bruce Hillman, MD, ACRIN Network Chair on his recent visit to ACRIN Headquarters.*

## PRINCETON INTERN ENGAGES IN “MONKEY BUSINESS”



*Mark Wertz, a senior majoring in ecology and evolutionary biology at Princeton University, served as an intern at ACRIN this summer. Mark calls Menlo Park, California home, and his post-graduation goal is to attend medical school back in California. Mark rounds out his academic experience playing water polo on Princeton's varsity team, as well as participating in intramural soccer and baseball. Here, he describes his ACRIN experience.*

This internship is offered through the Princeton Class of 1969 Community Service Fund and is sponsored by Princeton alumni and ACRIN Network Chair Bruce Hillman. I am a pre-med student and am currently studying for the August

MCAT. Orthopaedic surgery and sports medicine are definitely appealing to me, but radiology is another field that has sparked my interest, which is part of what led me to the ACRIN internship.

I have worked on a variety of projects this summer. First of all, I was involved in the design and implementation of several surveys, using a tool called Survey Monkey that distributes an online survey that recipients can quickly complete and that efficiently collates survey results. I helped design a National Lung Screening Trial participant retention survey and a survey for the developing knee osteoarthritis protocol. I also had the opportunity to work on a survey for the Radiation Therapy Oncology Group (RTOG) regarding image-guided radiation therapy target localization and imaging.

The survey that has taken up most of my time, however, was a survey on the Quality Assurance monitoring process that was introduced in the past year for two ACRIN trials. I was involved in the design, distribution, data collection, and analysis of this survey. I am helping to create a report on the results of this survey that will make suggestions about ways ACRIN can improve the monitoring process. I also developed and presented an interactive "Brown Bag Lunch" session on Survey Monkey for ACRIN and RTOG staff. Survey Monkey is a useful and effective tool, and it was exciting to help staff learn how to use it to improve processes and site support.

In addition to survey design, I was involved in an audit at UCLA for the National CT Colonography Trial that gave me great insight into the workings of ACRIN. I have found all of the projects I have worked on very rewarding and educational, and this summer has been a fantastic learning experience. I would like to thank all the staff members who got to know me this summer, who showed me around, who helped me out when I was a little lost, and who really introduced me to what ACRIN is all about. This internship was a great opportunity, and I will certainly recommend it to Princeton students in the future.

## ACRIN INVESTIGATOR HONORED BY LADIES HOME JOURNAL



*Etta Pisano, MD, addresses questions pertaining to DMIST results along with Constantine Gastonis, PhD.*

Etta Pisano, MD, director of the University of North Carolina Biomedical Research Imaging Center in Chapel Hill, was named a recipient of the first annual *Ladies Home Journal* Breakthrough Awards. The awards were created to "recognize doctors and medical researchers who are making lifesaving and life-enhancing discoveries in research, diagnostics, and treatment that we--patients and medical consumers--can benefit from right now." Dr. Pisano was lauded for her groundbreaking work as principal investigator of the Digital Mammographic Imaging Screening Trial (DMIST).

*Grant Renewal continued from page 3*

According to Donald Mitchell, MD, chair of ACRIN's Gynecology DSC, "A result of the previous grant renewal process was to focus the disease site committees and get them more actively involved in strategic planning. As a result, we are an active and strong committee, and becoming increasingly diverse." (See sidebar for more about the committee's work.) Over the past several years, all of the DSCs have worked on strategic planning to meet ACRIN's research objectives.

### ***How is ACRIN positioned to maximize its funding request?***

In tight budgetary times, ACRIN staff and researchers have worked hard to develop a strong organization that performs cutting-edge cancer research. According to Carl Jaffe, MD, Branch Chief of Diagnostic Imaging for the NCI, "ACRIN has been an organizational ground-breaker in the field of clinical trial imaging. For example, the

innovative originality of disease advocates in its IMPACT program has been cited by other clinical trial organizations as a model to emulate. Recognition of ACRIN's quality, commitment, and rigor in advancing imaging in clinical trials clearly eased the way for approval of moving forward with the process of re-issuing a Renewal of Funds by NCI's Board of Scientific Advisors at its meeting in June this year." ACRIN leaders will use the RFA to showcase the organization's strengths.

### ***How is ACRIN Future Funding Determined?***

When the NCI issues the Renewal of Funds Application (RFA) for ACRIN in September 2006, it will state how much funding ACRIN can apply for, and how many years. Early in 2007, the NCI will select a scientific peer review team whose members read ACRIN's renewal application and meet with ACRIN and BDMC

leadership, disease site committee chairs, and staff to learn about ACRIN's infrastructure and scientific work. Based on the team's evaluation, ACRIN is then funded at a certain level. The team also provides ACRIN with an analysis of the organization's strengths and weaknesses.

According to Dr. Mitchell Schnall, who will become ACRIN's Network Chair beginning with the new funding cycle, "I am confident that the teamwork of all the people who make up ACRIN will help us secure the funding we need to continue our important scientific work. We fill a unique niche in the cancer research community, and further development of our scientific objectives and collaboration with other groups will make our organization even stronger. I look forward to working with ACRIN researchers and staff for many years to come as we continue to improve the length and quality of life of cancer patients."



*A team of investigators known as the "ACRIN 6660 Truth Panel" convened at ACRIN headquarters to determine the reference standard of an overall diagnosis for participants on the pediatric whole-body MRI trial.*

*(From left to right) bottom: Sherri Spunt, MD, Allison Friedmann, MD, Mary Huang, MD top: James Meyer, MD, Murali Chintagumpala, MD*

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