

# ACRIN Research Associate Newsletter

American College of Radiology Imaging Network

Summer 2009

## What is an ACRIN PA Study?

ACRIN Pennsylvania (ACRIN PA) is essentially a “network within a network” of five Pennsylvania academic medical centers—University of Pennsylvania Health System, University of Pittsburgh Medical Center, Pennsylvania State/Hershey Medical Center, Fox Chase Cancer Center, and Thomas Jefferson University Hospital. It was created with funding received by the state from the tobacco companies under the Master Settlement Agreement in 1998 as partial compensation for medical costs incurred from the smoking of tobacco. Nearly 20% of this funding was earmarked for health research.

ACRIN PA was formed to conduct imaging studies of early-phase technology in an effort to advance the role of imaging in the detection and/or treatment of disease. The original research strategy outlined in 2004 called for trial development in three areas: magnetic resonance imaging (MRI) markers of knee cartilage integrity; dynamic contrast-enhanced (DCE)-MRI methods to



*The Imaging Core Laboratory uses advanced visualization and quantitative tools for 3D cardiac CT angiography analysis.*

determine the efficacy of cancer therapies, and a comparison of PET imaging agents in analyzing amyloid plaque in patients with Alzheimer’s disease.

Under the overall leadership of ACRIN network chair Mitchell Schnall, MD, PhD, the group has opened four trials since 2005. The results of the first study (*ACRIN PA 4001 MR Image Markers of Knee Articular Cartilage Damage in Osteoarthritis*) were submitted as an abstract to the Radiological Society of North America (RSNA) in April 2008, and Principal Investigator Tim Mosher, MD, anticipates submission to a peer-reviewed journal in late summer of 2009.

*ACRIN PA 4002* is a phase II study of patients with metastatic colon cancer evaluating tumor vascularity as measured by DCE-MRI. “The

*(continued on page 4)*

## RA Mentoring Tips: Informed Consent

*The following tips about the participant consent process are offered by Monene Kamm a research associate at the The Barrett Center in Cincinnati, Ohio.*

Present the informed consent document (ICD) to the potential patient far enough in advance of the enrollment visit to allow him or her to:

- read the ICD carefully
- discuss possible participation with family, friends, and/or physician
- ask questions and get answers
- have adequate time to make an informed decision.

Informed consent is an ongoing process of educating research participants, starting from the time of recruitment and continuing throughout their study involvement. It is important for us, as research associates, to continually communicate with our study participants in order to ascertain their continued consent.

### Inside:

- 2009 ACRIN Fall Meeting details
- An RA’s perspective on taking the SoCRA exam
- A data management pointer
- The Jo-Ann D’Amato Award of Excellence

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## Save the Date: Fall Meeting to Celebrate 10 Years of Excellence in Research

Please mark your calendar for the day-long RA educational session at the 2009 ACRIN Fall Meeting on Wednesday (note day change), September 30, at the Ritz-Carlton, Pentagon City, in Arlington, VA.

The RA Executive Committee members met at ACRIN headquarters in April to plan a day packed with information, blasts from the past, and highlights of the last 10 years. Basic RA training will be available again, as well as guest speakers, clinical slide presentations, and fun-filled activities. One of the activities will require you to have a business card, or some type of card with your contact information included. Don't forget to pack one!

A luncheon is a traditional part of the day that allows us to mingle and catch up with longtime friends and establish new relationships.

Again, remember your business cards. See you in September!

## A DM Pointer: Handling Queries for Participant Completed CRF's

ACRIN data management occasionally sends out queries related to participant-completed forms and questionnaires. For example, queries are being sent to the research associates (RAs) at sites participating in the National Lung Screening Trial due to the significant number of participant-completed forms generated. A common question from site RAs is "How do I handle responding to the query if the participant obviously answered incorrectly?" Following are several key points regarding how to handle any type of form completed by the study participant:

- All form revisions should be handled per the Good Clinical Practice (GCP) E6 Guidance.
- The RA should first verify that the participant's response was entered into the database correctly. If the information is correct, report this on the Z1 form. Sign, date and return the form to ACRN.
- If the change cannot be confirmed with the participant for some reason (e.g., the questionnaire was completed too far in the past or contact with the participant cannot be made) this also should be communicated on the Z1 form. Sign, date and return the form to ACRN.
- The form can be changed only 1) if the participant makes the change themselves, or 2) an RA makes the change the participant has confirmed and records details of the participant conversation in the progress notes.
- If a revision is made, the participant completed questionnaire must accompany the Z1 form response.

Contact an ACRIN data manager should you have any questions about the above process or any other data management related questions.

## Request for Photos: Be a Part of ACRIN's Celebration

It is only fitting that as we recognize ACRIN's 10th anniversary of conducting medical imaging clinical trials, we acknowledge all of those who have contributed to the effort. To accomplish this and have some fun, we are asking research sites to send photos of individuals (past and present) who have played a role in the operation of ACRIN trials. The photos will be included in a video presentation that will be featured during the Research Associate Educational Session, scheduled for Wednesday, September 30, at the 2009 ACRIN Fall Meeting in Washington DC.

So, take a few photos of your site team and forward them to us; also include any photos you may have from past meetings. Don't forget the PI, the research assistant, imaging staff—anyone who lends a hand. Be sure to identify the site, the particular trial or event (if appropriate), the persons in the photos, and the year the photo was taken (if known).

Please forward the photos to Cindy Cobb ([ccobb@lifespan.org](mailto:ccobb@lifespan.org)) This will be a fun visual walk down Memory Lane. Thanks to all for your contributions!

## Taking the SoCRA Exam: One RA's Experience



I had often thought about taking the Society of Clinical Research Associates (SoCRA) certification examination. To be recognized as a professional in research and have CCRP (Certified Clinical Research Professional) after my name would be a big accomplishment for me. ACRIN was offering the opportunity to sit for the test at last year's ACRIN Fall Meeting. I asked myself, should I take the exam? Yes, was my answer!

I became a SoCRA member and then registered for the exam. Shortly thereafter, I received my study materials. That's when reality hit me. I read the first few pages of the code, shut the book, and thought, "Why am I doing this to myself?" I didn't open the book again for another 2 months! Luckily, several of us in my department were taking the exam and we purchased study flash cards that were extremely helpful. I made up my mind to revisit the book. I studied every night for months. My family supported me but suffered the consequences of having a

mom studying for an important exam. They couldn't wait for me to take the test so they could return to a normal life.

Finally, the "big test day" arrived. I looked at the first two questions and thought to myself, "Oh, no... I don't know the answers!" I persevered and after 2½ hours, I completed the exam. I left the room not knowing how I had done. I found the exam very challenging, but my experience as a research associate definitely helped, as did the study materials. Four weeks later, "the letter" came in the mail. I couldn't believe how scared and excited I was to open that letter. My whole family stood around me. They were just as anxious to see my results. I didn't even read the whole thing. I skipped right to the part about my score—I passed. I was both excited and relieved! We had a great time celebrating.

With many hours of study time behind me and my family life back to normal, I am proud that I can now sign my name:

**Diane Romano, RTRM CCRP!**

### SoCRA Exam Again Offered

The RA Executive Committee has again made arrangements for the SoCRA certification exam to be offered in conjunction with the ACRIN Fall Meeting. The exam will take place on Tuesday, September 29, from 2:00 to 6:00 PM at the Ritz Carlton Pentagon City in Arlington, VA. The registration deadline is August 18. For more information, [click here](#) to visit the SoCRA Web site.

## Acronyms Associated with INDs

<b>IND</b>	Investigation New Drug
<b>CBER</b>	Center for Biologics Evaluation and Research
<b>PHS</b>	Public Health Service
<b>BA</b>	Bioavailability (study)
<b>BS</b>	Bioequivalence (study)
<b>OTRR</b>	Office of Therapeutics Research and Review
<b>CDER</b>	Center for Drug Evaluation and Research
<b>QC</b>	Quality Control
<b>FDA</b>	Food and Drug Administration
<b>CMC</b>	Chemistry, manufacturing and control
<b>COA</b>	Certificate of Analysis
<b>API</b>	Active Pharmaceutical Ingredient

The ACRIN Research Associate Newsletter is developed in cooperation with the RA Executive Committee and ACRIN Headquarters and distributed to ACRIN's research community.

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## Jo-Ann D' Amato Award of Excellence

The ACRIN Research Associate Executive Committee seeks nominations for the fourth annual Jo-Ann D'Amato Award of Excellence. Established in 2006, the award recognizes an ACRIN research associate who best exemplifies the values that guided Jo-Ann and made her a valuable asset to ACRIN and a much beloved friend and family member.

Candidates should be nominated based on the following criteria:

- Professionalism in their role
- Performance as a research associate
- Compassion for patients
- Community service

The deadline for nominations has been extended to August 15.  
*See page 5 for more information.*



*ACRIN network chair Mitchell Schnall, MD, PhD talks with RA Executive Committee members about committee goals during their planning meeting at ACRIN headquarters in April.*



*RA Executive Committee member Monene Kamm from the University of Cincinnati chats with ACRIN data managers Glenna Gabrielli and Lindsey Dymond.*

*(PA Study - Continued from page 1)*

novelty of the technology and the relatively restrictive eligibility criteria continue to pose challenges for subject recruitment,” states Principal Investigator Mark Rosen, MD, PhD.

The research focusing on Alzheimer’s disease includes two companion PET protocols (*ACRIN PA 4003 and 4004*). Although essentially the same, they involve two separate <sup>18</sup>F-fluoride compounds, one being developed at the University of Pennsylvania and the other at the University of Pittsburgh. The study’s goal, according to Principal Investigators Steven Arnold, MD,

and James Mountz, MD, PhD, is to evaluate the ability of these new amyloid ligands to distinguish patients with a clinical diagnosis of Alzheimer’s disease from cognitively normal individuals. An <sup>11</sup>C PET imaging compound will serve as the benchmark at both institutions, so that all subjects will undergo two PET scans as part of their study participation.

The most recent trial to be developed considers the use of imaging in the emergency department (ED). The *ACRIN PA 4005 Coronary CT Angiography* study will randomize low-risk subjects with potential acute

coronary syndromes to either a traditional “rule out” care arm or a computed tomography angiography (CTA) arm. A very similar single-site trial conducted by co-principal investigators Judd Hollander, MD, and Harold Litt, MD, PhD, at the University of Pennsylvania suggested that coronary CTA could be safely used to discharge low-risk patients home from the ED, decreasing the length of time certain patients must stay in the ED and considerably increasing ED efficiency.

For more information about these trials, visit the ACRIN Web site.

## Request for Nominations

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# JO-ANN D'AMATO AWARD OF EXCELLENCE

### Eligibility:

Award recipients must have been an ACRIN research associate for at least one year. In addition, they must be presently working on two or more ACRIN supported projects or devoting at least 50% of their time and effort to an ACRIN project.

Candidates should be nominated based on the following criteria:

- Professionalism in their role
- Performance as a research associate
- Compassion for patients
- Community service

[Click here](#) to go to application and instructions on the ACRIN Web site.

Nominations must be received or postmarked no later than Saturday, August 15 2009.

The award presentation will be at the 2009 ACRIN Fall Meeting.