

What Brings Research Associates to the ACRIN Fall Meeting?

One-on-One Interviews by Wanda Manfori, Roving Reporter

At first, being assigned the task of interviewing research associates (RAs) attending the 2009 ACRIN Fall Meeting as a “roving reporter” seemed daunting. Without any journalistic background to draw from, I took on the task for fun but also to see if I was up to the challenge of working beyond my comfort zone. It seemed pretty simple and straightforward, needing to ask RAs only two questions—why do they attend the ACRIN Fall Meeting and what brings them back?

Erin Nekervis

Between sessions, I quickly scanned the conference room looking for my first potential victim. As I boldly approached my first interviewee, Erin Nekervis from Northwestern University, I realized that I probably should have brought a recorder instead of trying out my speedwriting skills with pen and paper. What started out as a seemingly formal interview ended up being more of a friendly chat.



Laura Tuttle, MA, accepts the Jo-Ann D'Amato Award of Excellence from Network Chair Mitchell Schnall, MD, PhD and RA Executive Committee Chair Wendy Smith BS, RT(R) (CV), CCRP.

Erin has been the Research Coordinator for the National Lung Screening Trial (NLST) for the past 6 years or so and has attended the ACRIN Fall Meeting every year since then. When she attended for the first time, she met an RA from Vanderbilt University who later became one of her closest friends. The reason she keeps coming back is for the chance to meet up with old friends. However, she notes that people she met before were no longer around, including her friend from Vanderbilt.

Lena Marra, MA

Moving on to the next group, I approached Lena Marra. Lena has been an RA for about 25 years. She is Director of Research for the Imaging Science Laboratories at Mt. Sinai Medical Center in New York. Said Lena, “It is good once a year to meet with ACRIN RAs, see old friends, and to be able to discuss difficulties and problems we have with our studies.”

James Pool, Jr., BS

James Pool, Jr. from the University of Michigan claims to be an NLST “survivor.” As the NLST trial has been winding down, other RAs have moved on to other projects. As one of the “surviving” team members from the NLST project, he was given the opportunity to attend the ACRIN Fall Meeting this year. The event was a much-anticipated one for him and he was very much looking forward to attending the RA Boot Camp. His goal is to learn all the ropes and to become a full-fledged RA. He attended all the RA educational sessions and found

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Laura Tuttle, MA, Receives 2009 Jo-Ann D'Amato Award of Excellence

Dr. Mitchell Schnall, ACRIN Network Chair, presented the fourth annual Jo-Ann D'Amato Award of Excellence to Laura Tuttle, MA, from the University of North Carolina during the RA luncheon at the 2009 ACRIN Fall Meeting. Laura received the highest scores of a group of exceptional nominees. Her nomination by an ACRIN staff member was accompanied by a letter of recommendation from one of her colleagues. The nomination clearly demonstrated Laura's professionalism, performance as an RA, compassion for patients, and community service, proving that she exemplifies the spirit of the Jo-Ann D'Amato Award of Excellence. Also noteworthy, Laura had a baby girl 4 weeks prior to receiving the award. Congratulations to Laura on both counts!!

The Jo-Ann D'Amato Award of Excellence is given annually to honor the memory of our beloved friend and colleague Jo-Ann D'Amato, who clearly set the standard for this award based on her dedication to ACRIN's mission and her personal values.

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- Glioblastoma Trial Highlight
- Accrual Subcommittee Formed
- Educational Session Wrap-up

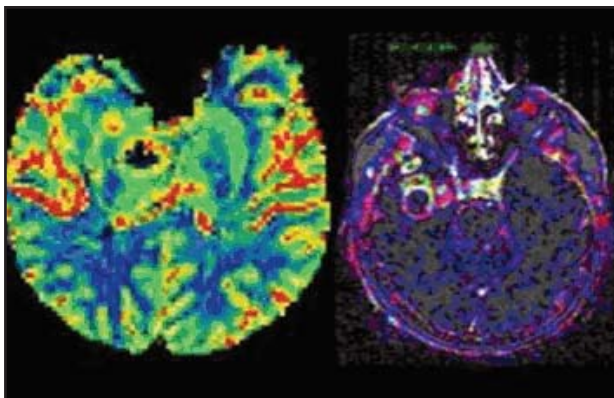
ACRIN[™]
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Important Glioblastoma Study Underway

ACRIN 6684: Assessment of Tumor Hypoxia in Glioblastoma with PET and MRI

Objectives and Design

The first five sites have activated a Phase II assessment of tumor hypoxia in glioblastoma multiforme (GBM) using 18F-fluoromisonidazole (FMISO) with PET and MRI. The trial will recruit 50 adult patients with newly diagnosed GBM who have residual disease documented by gadolinium-contrast MRI following surgery and are scheduled for standard chemoradiotherapy.



The images above demonstrate the MRI perfusion of the brain scanning technique that will be used in the ACRIN 6684 trial.

According to Bernadine Dunning, ACRIN 6684 Project Manager, “GBM is the most common and, unfortunately, most aggressive type of primary malignant brain tumor. Despite treatment with surgery, radiation, and chemotherapy, the overall prognosis is poor, with a median overall survival of less than 15 months. Better therapies are desperately needed.”

Participants enrolling in this trial will undergo FMISO PET and MRI scans prior to the start of chemoradiation (baseline), at 3 weeks after the start of chemoradiation, and at 4 weeks after the completion of chemoradiation. To test reproducibility of FMISO PET, the first 15 participants will undergo two FMISO PET scans within 1 to 7 days of each other prior to starting chemoradiation.

Scientific Background

In addition to being strongly associated with angiogenesis and tumor growth, low oxygen levels (hypoxia) have been shown to reduce the efficacy of radiation and chemotherapy and may be indicative of a more aggressive tumor type. Radiolabeled FMISO’s binding within hypoxic cells have made it an increasingly studied agent for measuring tissue oxygenation in tumor cells. This trial is therefore designed primarily to determine the association of baseline FMISO PET uptake and MRI parameters with overall survival following treatment.

“Being able to better characterize and target the mechanisms of GBM hypoxia could lead to improvements in therapy for this deadly disease,” Dunning anticipates. “By better understanding the extent of tumor hypoxia and changes in regional tumor hypoxia with treatment, more effective and patient-specific therapies could be devised to halt GBM growth and optimize therapies and improve survival.”

Status and Challenges

In the initial group of approved sites (see sidebar), the study is expected to activate in March 2010. Reflecting on her involvement with the University of Washington site,

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First Sites to Activate ACRIN 6684

Congratulations to the University of Washington for being the first site participating in the ACRIN 6684 trial to complete all start up activities. The site team has now turned its attention to recruiting the first trial participant.

First Site to Activate ACRIN 6684

- University of Washington

Other Sites Soon to Activate

- Massachusetts General Hospital
- University of Pennsylvania
- Mount Sinai Hospital and Medical Center
- Duke University

We look forward to all of the above sites activating by March 31. In addition, five sites are in the initial start up stages and are expected to activate the trial in May 2010. Please contact recruitment specialist Heather Homick, MPH (hhomick@acr-ars.org) should you want more site participation details.

Tips From the Mentors

In an ongoing effort to assist new RAs with all aspects of ACRIN protocol management, members of the Mentoring Subcommittee have offered valuable tips through this publication. This issue’s advice comes from Tracy Sitton-Petro, CTR, CCRP, with Clinical Radiologists, S.C. in Springfield, IL:

1. When completing case report forms, keep distractions to a minimum. It’s easy to make simple, but potentially significant, errors when you’re distracted.
2. Make sure all IRB submissions are completed in a timely manner. Lapsed continuing reviews, delayed adverse event reporting, etc, can cause major problems for your site.

New Accrual Subcommittee Seeks Input From RAs

Despite the central role RAs play in the recruitment process, past investigations into obstacles to clinical trial patient enrollment have rarely involved the RA perspective. Tracy Sitton-Petro, CTR, CCRP, Co-Chair of the new ACRIN Accrual Subcommittee, is working to change that. Along with Chair Peggy Anthony (patient advocate for the ACRIN Thoracic Committee), Sitton-Petro is involved in an effort by members of the ACRIN Patient Advocacy and RA Committees to join their collective knowledge about and interest in helping to increase patient accrual to ACRIN clinical trials.

Toward its overall goals of identifying the major accrual barriers across all types of participating sites and to develop strategies to overcome these barriers, the newly formed Accrual Subcommittee is developing a site survey additionally aimed at discovering best practices for reaching accrual

“This survey has been developed to explore the factors that influence the decision of patients regarding clinical trial entry, from the perspective of both the RA and the site PI.”

Tracy Sitton-Petro,
CTR, CCRP

goals. According to Sitton-Petro, “A patient’s decision to enter into a clinical trial has been typically explored from the perspectives of patients and their physicians. This survey has been developed to explore the factors that influence the decision of patients

regarding clinical trial entry, from the perspective of both the RA and the site PI.”

“Once the answers are known, the site and sponsor can work more closely as a team to resolve recruitment obstacles, improve accrual rate, and better plan for future protocols.”

Suzanne Lenz, MA, CCRP

RAs should have received the survey by e-mail in February, and again in March 2010. Taking the time to complete this survey will ensure that your valuable input is incorporated into the subcommittee’s recommendations. Watch for summaries of the data collected from this survey in future issues of the ACRIN RA Newsletter.

The ACRIN Accrual Subcommittee will also be instrumental in the development of an ACRIN Participant Screening Log to gather data about why potentially eligible participants either were eventually determined ineligible or decided not to take part in a trial. Information derived from the tool will be used to address across-site barriers and assist the protocol team in making protocol revisions to meet accrual goals. As subcommittee member Suzanne Lenz, MA, CCRP, from Dartmouth-Hitchcock Medical Center states, “Once the answers are known, the site and sponsor can work more closely as a team to resolve recruitment obstacles, improve accrual rate, and better plan for future protocols.”

Accrual to ACRIN Trials: Your Input Is Needed

Site research associates and principal investigators who worked on one or more of the 16 ACRIN studies that have closed to accrual were invited to provide their participant recruitment experience by completing a survey developed by the ACRIN Accrual subcommittee. If you have worked on an ACRIN trial and did not receive the survey e-mail request, please contact Heather Homick (hhomick; 215-574-3194).

Also, please contact any member of the accrual committee with future suggestions to enhance participant enrollment in ACRIN trials.

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10th Annual RA Educational Session at ACRIN Fall Meeting - Wednesday, September 30, 2009

Congratulations to all! This year's ACRIN Fall Meeting Research Associate (RA) Educational Session celebrated 10 years of solid imaging education and research. The 10th annual RA educational session was held at our home base—the Ritz Carlton, Pentagon City, in Arlington, VA. There were approximately 100 participants; thank you to all who attended. The theme for this year's meeting was "10 Years of Advancing Imaging Research."

Morning Sessions

To begin our meeting and celebration, Henry (Hank) Brasteter shared "10 years of tops." This interesting and funny look back was a great way to lead off a very rigorous day of education.

The morning continued with great presentations by Dr. Hani Nabi and Dr. Terrance Wong regarding PET imaging of the chest



Patient advocate Peggy Anthony, RN, MHS, CNOR, presented strategies for consenting terminally ill patients on to a clinical trial and listens to questions and comments from research associates regarding this topic.

and lung cancer. Both talks were designed to give ACRIN RAs a better understanding of the work that is being done in at least two ACRIN trials (6668 and 6678). We wound out the morning with two very strong talks.

Peggy Anthony from the Patient Advocacy Committee shared her experiences with clinical trials and her perspective on the sensitivity needed when recruiting the terminally ill patient. Such sensitivity is crucial because we are often recruiting patients at a very difficult time for them, possibly right after they've received the news that they have cancer. Jim Gimpel from the ACRIN Imaging Group brought us all up to speed on TRIAD (ACRIN's image management system) and all of its many features.

Lunch Program

During our lunch break, we shared a walk down memory lane with a video of friends and faces from ACRIN past and present. Cindy Cobb of the RA committee, with the help of many of you, put together a video of pictures of past meetings, ACRIN staff, and ACRIN sites. Dr. Mitchell Schnall (ACRIN Network Chair) presented the fourth annual Jo-ann D'Amato Award of Excellence to Laura Tuttle. Laura was chosen from the group of nominations for her expertise and dedication to ACRIN's mission at the University of North Carolina. This award continues to showcase the great work of ACRIN RAs and honors the memory of our dear friend and colleague.

Afternoon Sessions

After lunch, the meeting continued with a presentation by Dr. Paula Jacobs and Dr. David Mankoff regarding ACRIN trials that involve the use of investigational agents under the auspices of an investigational new drug (IND). ACRIN has been pursuing more and more trials using new agents that require investigation under an IND application. Tracy Sitton-Petro and Suzanne Lenz, both from the RA Committee, wrapped up our time as one large group with ACRIN's Top 10 (a Dave Letterman-like Top 10) and an overview of the ACRIN Site Operations Tool used to help RAs manage their data.

The RA Boot Camp, organized and presented by the RA Mentoring Subcommittee, was again offered. Monene Kamm and Tracy

Sitton-Petro spearheaded the camp. This session is dedicated to providing research basics to those just starting out on ACRIN trials. The feedback from those who attended was



RAs Pamela Angelus, MSN, Pam Allen, RN, and Darlene Frasher, MSN, RN network at the ACRIN Fall Meeting.

very positive, and we plan to continue offering this session each year to support our new RAs. Meanwhile, in a session running simultaneously with the RA Boot Camp, the old-timers (experienced RAs) were brought up to date on the RA subcommittees' activities, and those in attendance were encouraged to become involved. Whether or not you attended this session, if you are interested in working on one of these committees, please complete the ACRIN RA Subcommittee Questionnaire on the ACRIN Web site (www.acrin.org/committeesresearchassociates/subcommittees/tabid/248/Default.aspx) and forward it to Tina Taylor (ttaylor@acr.ars.org) at ACRIN.

To provide RAs with the ability to ask protocol-specific questions in an informal venue, we continued the tradition of roundtable discussions. Representatives from ACRIN administration, data management, imaging, and regulatory departments were available to support each RA's specific request.

We appreciate the feedback we received on the meeting evaluation forms; please know that we will keep your comments in mind as we plan next year's meeting. If you didn't complete an evaluation form and have any suggestions for future meetings, please e-mail them to Lorna Beccaria (LornaB@ocsi.us).

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them very informative. The RA Boot Camp remains a well-attended session during the yearly ACRIN Fall Meeting, because it provides basic training especially for new RAs.

Miriam Abu, MD, MPH

I crept into the RA Boot Camp session before it started and found Miriam Abu. She was a very pleasant lady and after we introduced ourselves, we found out we are both MDs. Miriam is from Weill-Cornell Medical Center. She is relatively new as an ACRIN RA. Her institution recently got initiated as an ACRIN site, and she was definitely excited to start her duties as Coordinator for an ACRIN trial. She attended the RA Boot Camp to learn more about becoming an ACRIN RA and to be well-prepared for the job.

Anna Fagan, BS, and Kathleen Thomas, BS

Scouting the Boot Camp attendees for my next intended interviewee(s), I found Anna Fagan and Kathleen Thomas, both from the University of Pennsylvania. Anna considers herself a “newbie,” being recently brought into the ACRIN PA 4002 liver trial. Attending the ACRIN Fall Meeting was a welcome opportunity. It gave her a chance to meet face-to-face people with whom she talked on the phone and communicated through e-mail, or simply just knew by name. She found the ACRIN meeting educational, fun, and entertaining. Like James, Anna attended the Boot Camp session so she can achieve her goal of becoming a full-fledged RA.

Kathleen, however, is a veteran ACRIN RA, having been involved with ACRIN trials for the past 6 years. She is the coordinator for ACRIN Trials 84 and 88. “I always learn something new when I attend the ACRIN Fall Meeting,” said Kathleen. She was particularly impressed with the speaker from the Patient Advocacy Committee, Peggy Anthony. Listening to this presentation, titled “Sensitivity

in Recruiting Terminally Ill Patients,” made her step back and remember how to deal with subjects and patient volunteers, especially those with cancer. Furthermore, she stated that there are “new faces” all the time. People she met in prior meetings were no longer around.

Summing Up and Looking Ahead

In summary and pondering on the responses to the interview, our RA attendees placed much emphasis on the educational and learning aspects of the ACRIN Fall Meeting but wanted to relax and have fun as well. Mostly, it was a welcome opportunity to make new acquaintances and to catch up with old friends.

What was the experience like for me? Despite the fact that I felt amateurish in my attempts at reporting, the atmosphere was relaxed and friendly. It gave me time to get to know other RAs and find out about their thoughts and expectations regarding the ACRIN Meeting. Given the chance to do it next year, I would attempt to conduct the interviews in a more professional manner—complete with a tape recorder, digital camera, and the like. It would be great to come up with an article in which we can relate to the RAs on a more personal level.

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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Lanell Peterson stated, “It has been exciting to assume the role of RA in the ACRIN 6684 trial using PET imaging of glioblastoma patients at our facility. The collaborative work of Dr. James Fink, our principal investigator (PI) for 6684, and the entire ACRIN team has made the process of moving the trial forward practically seamless. My role will involve a partnership with many people in several departments to accommodate the needs of the research patients and to fulfill the aims of the project. We are all eager to get started.”

As with any clinical trial whose resulting data may benefit patients diagnosed in the future more than current enrollees, meeting recruitment goals for 6684 is expected to present challenges. Heather Homick, ACRIN Recruitment Specialist, addressed the efforts being pursued to meet these challenges. “Although recruitment for 6684 may require added efforts from the site study team,” stated Homick, “the results of this trial will be reward enough for going that extra step in obtaining patient participation.” ACRIN is committed to assisting sites in their accrual process by holding on-site meetings with the study PIs, RAs, and oncologists to review and discuss their specific accrual process. Materials have been developed to assist sites in making the recruitment process easier, and new ideas are always welcome.

The process of screening 5 additional sites, in which the study will activate no later than June 1, 2010, is now underway. Sites interested in applying to participate in this study are encouraged to contact Bernadine Dunning at bdunning@acr-arrs.org.