

ACRIN Research Associate Newsletter

American College of Radiology Imaging Network

Fall 2008

New Challenges We Face as an RA: Can We Rise to the Occasion?

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Among the current challenges in the life of a Research Associate (RA), I find patient recruitment and enrollment to be the most daunting. Every experienced RA is aware that the key to a clinical trial's success is meeting the study's accrual goals; **enrolling the required number of subjects, according to a specific time frame.** Much of the responsibility for reaching the accrual goal lies in the hands of the principal investigator (PI), but a large part of the burden also falls on the RA's shoulders. Delays in accrual could mean extension of the trial, the incurring of additional expenses, or collapse of the project due to financial constraints. Therefore, it is the responsibility of the RA to be well informed and current on the safety issues and risks associated with the imaging modality utilized in his or her study. The RA's response to the questions posed by a perspective study participant directly affects the ability of the site to recruit successfully.

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The numerous complex factors that affect patient enrollment include the large number of studies competing for the same and limited number of patients; the rules governing patient recruitment and enrollment; and most importantly, patient concerns about being a participant in a research trial. The public is aware of drugs that have been tested, FDA-

approved, and then removed from the market due to unfavorable side effects and/or safety concerns. Additionally, other drug research and development issues that have been played out unfavorably in the media further fuel a patient's/subject's concerns about safety in clinical trial participation.

Generally, imaging-based clinical trials (CT or MRI), have not enjoyed as much notoriety as drug-related studies and clinical trials in terms of safety issues. However, recently published articles have reported a link between radiation exposure in CT and increased risk for cancer as well as the occurrence of nephrogenic systemic fibrosis (NSF)² in patients who had contrast-enhanced MRIs. As a result of these reports, imaging safety has become the focus of attention not only in the media but within the medical community as well.

In response to these concerns, our study team works hard to make sure that study-related documents and protocol design reflect the new safety issues. Although we have not felt the impact in terms of a decline in patient/subject enrollment, safety-related questions have increased. *What is the increased radiation exposure with a CT scan versus an x-ray? Are there any side effects associated with MRI? What is NSF?* We have noticed questions becoming more in depth, oftentimes requiring lengthy and detailed explanations, not only from the RA but from the PI and co-investigators as well. Potential study subjects are encouraged to consult with family members or their doctor to ensure their understanding of the Informed Consent before agreeing to participate.

The ever-changing world of imaging does
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Tips from the Mentors!

This is the debut of a feature in which the members of the Mentoring Subcommittee offer advice to RAs new to ACRIN or to clinical research in general. Here are two initial examples of such advice:

1. Always document your conversations with ACRIN staff when obtaining special protocol instructions. This can be handled in a number of ways:

- by requesting a follow-up e-mail from the ACRIN staff person detailing the information provided
- by recording handwritten notes from a conversation
- by documenting information on a electronic or hard copy form that you have developed for the purpose of documenting protocol discussions.

Always remember to date and sign your documentation. This will help you stay organized as well as be of great value during an audit.

2. Remember to use good clinical practice (GCP) on ALL of your protocol documentation. Lack of GCP is one of the most common audit "dings."

Stay tuned for ongoing mentor tips on all aspects of ACRIN protocol management in future newsletter issues.

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Reporting In!

Summary of the June 2008 RA Executive Committee and RA Subcommittees Meeting at ACRIN HQ

The RA Executive Committee met on June 24th at ACRIN headquarters in Philadelphia to discuss goals and plan activities for 2008. Members also selected the 2008 recipient of the Joann D'Amato Award of Excellence. Thank you to all who submitted nominations for this special award. This year's award will be presented during the RA Education session on October 2nd at the ACRIN Fall Meeting.

Review of Survey Results

Based on their review of the latest RA survey results, RA Executive Committee members are finalizing a paper to be submitted to a journal before the end of 2008. In discussing topics for future papers, the committee drafted an outline for a paper to be submitted in spring 2009 entitled, "Strategies for Increasing Enrollment in Imaging Trials." The RA Executive Committee appreciates the efforts of all the RAs who submitted surveys and welcomes any topic suggestions for future RA papers

New Subcommittee Members Welcomed

Six RA subcommittee members (see page 4) joined the Executive Committee on June 25th for a day of meetings and activities. After being welcomed by Charlie Apgar of ACRIN, the combined group was given a tour of the ACRIN facilities. Members took advantage of the opportunity to meet many of the ACRIN staff and ask questions regarding the imaging core laboratories and other facilities.

The day continued with a presentation by two members of the Cancer Coalition, which is housed in the same building as ACRIN headquarters. The presentation focused on their group's activities and led into a discussion of potential collaborations including educational opportunities. During an enjoyable meet-and-greet lunch with the ACRIN staff, RAs had the chance to put faces along with names and to finally meet many of the people that they e-mail or talk to daily.

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ACRIN Staff and members of the RA Committee enjoy a lunch break together at ACRIN headquarters. From left to right: Wanda Marfori, Jamie Downs, Tracy Sitton-Petro, Maria Oh, Monene Kamm, and Lynn Werner

Acronyms (9/08)

An initial glossary of research trial acronyms was listed in the RA Newsletter earlier this year. Occasional additions, such as the following, will appear in future issues as the need becomes apparent. The updated comprehensive list can be accessed at [www.acrin.org/committees/RA Committee](http://www.acrin.org/committees/RA%20Committee). As always, we hope that this tool will help you connect the acronym with the appropriate imaging-related term or organization.

CCOP: Community Clinical Oncology Program

CGOP: Cooperative Group Outreach Program

NCI CCC: National Cancer Institute Comprehensive Cancer Center

ICH: International Conference for Harmonization

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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ACRIN headquarters is supported by Grant CA80098 from the National Cancer Institute.

Dear ACRIN

In keeping with our goal of assisting RAs with all phases of protocol data management, here are answers to some questions most commonly posed to ACRIN data managers.

Dear ACRIN,

How can I obtain extra labels?

You may print your own labels from the ACRIN Web site (www.acrin.org) by performing the following steps:

- From the ACRIN home page, select the link to **Data Center Login**.
- Select one of the following: **ACRIN - Protocols** or **ACRIN 6666**.
- Enter your **Login** and **Password**, and select **Login**.
- Select your **Institution Number** from the menu provided.
- From the **Main Menu**, select: **Extra Label**.
- On the **Extra Label** screen, enter the **Study No.** and **Case No.**, and then select "Submit."

This utility was optimized to print 1" X 4" labels (2 rows of 10 labels per sheet). A standard label is Avery 5161 or equivalent.

Dear ACRIN,

What is a reader ID and how can I obtain one?

A reader ID is an ACRIN identifier that is unique to a site's principal investigator and/or co-investigator(s). This ID is required in order to complete some of ACRIN's case report forms (CRFs).

A reader ID may be obtained from the ACRIN Web site (www.acrin.org) by performing the following steps:

- From the ACRIN home page, select the Protocol Summary Table.
- Select the protocol your site is conducting.
- From the left side of the protocol-specific page, select **Protocol Application and Site Application Materials**.
- From the right side of the subsequent page, select **Username and Password and Reader ID** form and print out a copy of the form.
- Follow the instructions on the form, completing the information in the shaded boxes, and e-mail the form to username@acrin.org.

Should you have any questions, please contact the administrative assistant listed for the protocol of interest.

Challenges

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pose a new and added dimension to the clinical trial patient recruitment and enrollment process. Have we risen to the occasion? Definitely; we have met the challenge head-on. In educating ourselves regarding these new concerns we have educated potential subjects and allayed (without diminishing the relevance of these concerns) their fears in the process.

Following are two online references that I found particularly of interest. The first provides a review of presentation about radiation dose at an International Symposium on Multidetector-Row CT: <http://www.auntminnie.com/index.asp?Sec=sup&Sub=cto&Pag=dis&ItemId=81091&wf=2513>.

The second is information about Nephrogenic Systemic Fibrosis (NSF) at: <http://www.pathmax.com/dermweb/>.

Inquire, Inspire, Inform: Seeking Contributions to the RA Newsletter

The ACRIN Research Associate Newsletter provides a means for RAs to keep in touch with and support one another. To further develop this means of communication, the RA Executive Committee encourages you to consider submitting a contribution that can be shared in a future issue. The contribution can be anything from a few lines to a longer article on a topic in which you have a special interest. Articles from other sources you think the ACRIN RA community would find of interest can also be considered for inclusion in the RA Newsletter as long as permission is granted as needed.

Here are a few suggested topics:

- A day in the life of an ACRIN Research Associate
- Human interest story (no names please)
- New technology discussion
- Recruitment challenges and difficulties
- Ideas to boost recruitment
- Ideas to facilitate retention
- Helpful tips, shortcuts, and suggestions
- RA reflections on ACRIN meetings
- Questions for ACRIN staff
- Reviews of educational programs
- Requests for help with specific problems

Topics are not limited to these suggestions. Be creative with your contributions! Please forward your material by e-mail to Lynn Werner, chair of the Networking and Communications Subcommittee: (lynn.werner@uphs.upenn.edu). We look forward to hearing from you.

Introducing Subcommittee Members

A call was put out to recruit ACRIN research associates to serve on subcommittees of the ACRIN Research Associates Executive Committee. An impressive group of RAs stepped forward to volunteer and we are pleased to introduce them to the ACRIN RA community.

Dina M. De Palo, BA, CCRP, works in the department of general internal medicine at Rhode Island Hospital. She is the study coordinator for the cost-effectiveness assessment component of the ACRIN 6666 trial. She also supports other research related to breast cancer and infectious diseases.

Monene M. Kamm, AS, began her research career after her first two children started school and worked for ten years coordinating clinical microbiological studies for a contract research company. Now at the University of Cincinnati, for the past five years she has been coordinating both ACRIN clinical trials and industry sponsored trials.

Suzanne B. Lenz, MA, CCRP, became involved in clinical research after an 18-year career as an audiologist. She also was involved in electrophysiological and central auditory processing research going on to coordinate the pediatric and cochlear implant programs at the Dartmouth-Hitchcock Medical Center. In 2002, she became the study coordinator for the National Lung Screening Trial and continues to coordinate the trial's many follow-up activities.

JoAnn Lorenzo, MPA, from the Seattle Cancer Care Alliance has been actively coordinating ACRIN trials for the past six years and has been involved in research for the past nine years. She served as the lead RA for the 6667 trial where she worked closely with the national trial principal investigator, Constance Lehman, MD, PhD.

Wanda C. Marfori, MD, from UCLA, is a senior analyst in the public administration department of radiological sciences at the David Geffen School of Medicine. Wanda has been involved in radiology research in several capacities since 2002 and was instrumental in coordination of the National CT Colonography trial at UCLA and now has a lead role in the GOG 0233/ACRIN 6671 trial.

Ferdnand Osuagwu, Msc, MD, having obtained a medical degree in Nigeria and taught at the University College Hospital in Ibadan, Nigeria, Ferdnand accepted a position at UCLA as a visiting assistant research in pediatric neurology in 2005. The National CT Colonography Trial was the first ACRIN study he worked on and has gone on to support ACRIN 6673 and ACRIN 6671. Ferdnand is also the recipient of the 2007 Jo-Ann D'Amato Award of Excellence.

Reporting In!

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After lunch, each subcommittee met separately to brainstorm ideas and goals for 2008-2009. The results of these discussions, later shared jointly with the Executive Committee, included ideas for improved communication among RAs, stronger mentoring relationships, quality assurance activities, and, as always, opportunities for future education.

The day ended with a review of the proposed agenda for the 2008 ACRIN Fall Meeting. Some of the new subcommittee members joined the roster of planned speakers, and many of their innovative ideas were incorporated into the program.

The RA Executive Committee and RA subcommittees extend a special thank you to ACRIN for bringing us all together. It was wonderful to be able to share experiences and brainstorm about how we can better support both the ACRIN mission and the ACRIN RA.



RA subcommittee members pictured from left to right are (Back row) Suzanne Lenz, Ferdnand Osuagwu, Lisa Camacho, Mary Klaus Clark (Front row) JoAnn Lorenzo and Monene Kamm



From left to right: Mary Klaus Clark, Tina Taylor, and Lisa Camacho enjoy lunch at ACRIN HQ