

ACRIN Fall Meeting Wrap-up

Award Recipient

Wendy Smith, CCRP, chair of the ACRIN RA executive committee presented the second annual JoAnn D'Amato Award of Excellence to Ferdinand Osuagwu at the fall meeting luncheon held Saturday, September 29th. As Wendy announced



Photo courtesy of Clara Morales

Wendy Smith presents the Jo-Ann D'Amato Award of Excellence to UCLA RA Ferdinand Osuagwu.

when presenting the award, "the committee received four applications for three nominations this year, all for very hard-working, highly qualified research associates."

"Ferdinand was nominated for coming on board during a crisis and handling the challenges presented with great energy and enthusiasm. He led the UCLA team to recruit the highest number of participants on the West Coast into the CTC trail. Furthermore, he was described as intelligent, diligent, honest, ethical and kind, all of the qualities we look for in the award recipient."

Congratulations to Ferdinand Osuagwu!

Fall Meeting Wrap-up

The 8th annual RA session was held on Thursday, September 27th, 2007. Approximately 100 people were in attendance and overall it was a great success. The meeting was highlighted by presentations of interest for the general audience followed by breakout sessions geared for both the new and experienced RAs.

The day began with several very interesting talks regarding the CaBIG initiative and ACRIN's role in fulfilling the NCI's mission for data sharing and continuity between trials. Mid morning, new RAs were invited to attend RA Boot Camp. This session was dedicated to providing research basics to RAs who have recently started to support an ACRIN trial. The more seasoned ACRIN RAs participated in an activity regarding achieving personal accountability. While the two sessions were plagued by a noisy environment due to inadequate sound barriers, we thank all who participated despite the distraction.

After a wonderful lunch at which the RAs were welcomed by Mitchell Schnall, MD, PhD, ACRIN's new network chair, the afternoon continued with excellent talks to include: the development and availability of lay imaging descriptions created by the ACRIN Patient Advocacy Committee; everything you need to know about the Data Safety and Monitoring Committee; and a fun and informative session on the Myers Briggs Type Indicator.

See photographs from the ACRIN 2007 Fall Meeting on page 5.

In mid afternoon, once again, attendees divided into smaller groups to participate in protocol specific breakout sessions

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Newly Designed Web Site is Live

Don't forget to check out all the new features and capabilities of the updated ACRIN Web site. The design was developed to meet the specific needs of its users—imaging professionals and patients—and to provide ACRIN with a more sophisticated Internet presence. With the site's improved navigational system and additional functions, RAs can now locate specific categories of information with much less searching.

The newly configured Protocol Summary Table allows users to:

- Sort clinical trials according to protocol number, study type (organ site), imaging modality, and status of trial operation
- Filter a protocol table view according to study type, modality, and/or status

Additional key ACRIN information now available on the site includes:

- ACRIN committee descriptions, responsibilities, and member contact data
- ACRIN Data and Image Sharing Policy
- Lay descriptions of imaging exams developed by ACRIN's patient advocates
- Updated content for all existing sections

New functions will be incorporated in the site as the need arises. Check the Announcements section of the home page for ongoing details.

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Protocol Highlight: RTOG 0625/ACRIN 6677

ACRIN is currently collaborating with RTOG on a trial that investigates two treatment options for patients with recurrent malignant head tumors. The ACRIN component examines the role that imaging can play in evaluating treatment effectiveness. This trial is noteworthy because of its potential to identify not only whether the drugs investigated are effective and safe in this population, but also the specific reasons behind their success or failure.

RTOG 0625/ACRIN 6677 was activated on March 1, 2007, with an accrual target of 122 participants. As of November 15, 2007, 101 participants have been enrolled in the trial which is temporarily suspended to further enrollment for the purpose of RTOG completing an interim statistical analysis.

This trial involves administration of the anti-angiogenic drug bevacizumab, which is designed to cause tumors to shrink by interrupting the process of new blood vessel growth. It is thought that agents targeting this factor in

tumor growth can also make treatment with other chemotherapy agents more effective. The combinations of bevacizumab with irinotecan and with temozolomide are being compared in patients with malignant head tumors to test this theory. Neither of these agents has been effective in treating this population when used alone. However, they have been significantly effective when used in combination therapy.

All sites enrolling participants in the RTOG 0625/ACRIN 6677 trial will coordinate the trial's baseline MRI scan and send these images to the ACRIN image archive. In addition, a sub-set of sites will participate in the advanced study component to explore the potential role of perfusion MRI and MR spectroscopy as early indicators of response to treatment and as prognostic indicators.

MR spectroscopy is capable of providing chemical information about the tumor and its environment, including changes in cancer markers reflective of functional tumor changes. Perfusion MRI is capable of quantifying the contrast agent as it passes into the tissue, thus providing estimates of the transfer

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Perfusion MRI

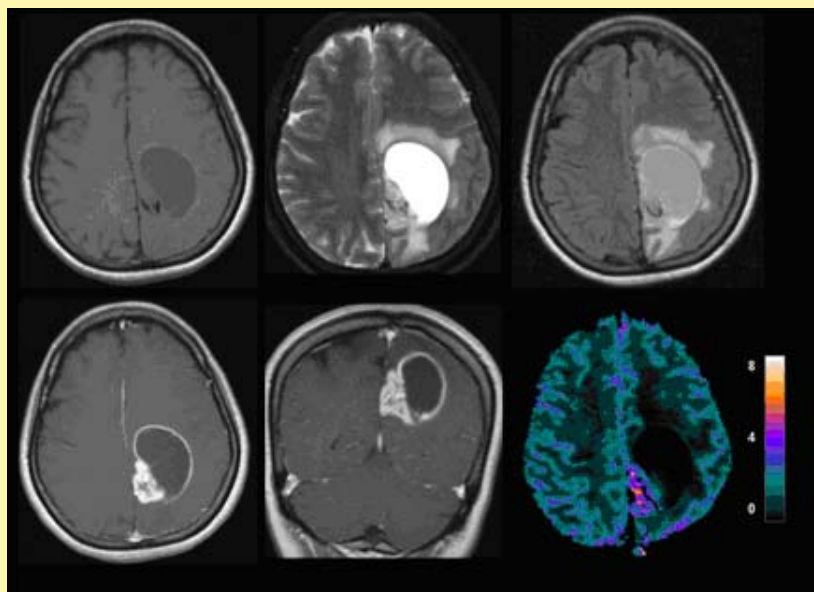
Perfusion-weighted imaging (PWI) encompasses both dynamic susceptibility contrast (DSC) MRI and dynamic contrast-enhanced (DCE) MRI. Both of these techniques are being used in the RTOG 0265/ACRIN 6677 protocol. In brain tumors, DSC MRI is most commonly used to measure cerebral blood volume and DCE MRI to measure vascular permeability. Both imaging techniques involve a bolus IV injection of a gadolinium-based contrast agent during continuous imaging of the brain.

DSC MRI - Cerebral Blood Volume

For DSC MRI, the arrival, passage through the brain, and wash-out of the contrast agent is tracked by the signal intensity-time curve for each voxel (three-dimensional pixel), providing an estimate of intravoxel contrast agent concentration. Relative cerebral blood volume (rCBV) and cerebral blood flow (CBF) are then evaluated on a voxel-by-voxel basis. These characteristics are not measurable using conventional contrast enhanced MRI. Of particular interest, rCBV has been shown to correlate significantly with tumor grade, may aid in differentiating post-treatment changes from tumor recurrence, and may predict early local recurrence or malignant transformation.

DCE MRI - Vascular Permeability

DCE MRI evaluates the vascular permeability to contrast agent by essentially measuring how "fast" the contrast is getting from point A to point B using a measurement called Ktrans. It has been demonstrated that Ktrans correlates with glioma grade and that a direct relationship exists between Ktrans and length of survival in high-grade gliomas. Because Ktrans may be greater in neoplasms with increased angiogenesis and vascular permeability, substantial changes in Ktrans very shortly after initiation of anti-angiogenic chemotherapy suggests that this tool may serve as an imaging biomarker for treatment response to angiogenesis inhibitors.



The bottom right image is a rCBV map, demonstrating substantially increased blood volume in the solid enhancing nodular component of a cystic tumor in the left parietal lobe.

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constant, blood volume, blood flow, and average blood vessel size. (For readers interested in a more technical description of perfusion MRI, please see the sidebar.) Both methods have the potential for providing more mechanistic information than the structural MRI routinely used to assess head tumor recurrence and treatment response. The ACRIN imaging aim includes a central reader study to assess the agreement between local interpretation and central interpretations within this same time period using the central read as the reference standard.

During the current statistical analysis period, no new sites are being approved to participate in the trial. However, ACRIN maintains a list of interested sites for follow-up contact at the time the trial is to be reopened.

For further information please contact ACRIN Project Manager Bernadine Dunning at bdunning@phila.acr.org.

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regarding ongoing ACRIN trials. The breakout sessions were devised to provide ACRIN RAs with an informal venue to discuss any issues regarding the trials they support. At each breakout session staff from ACRIN headquarters and the ACRIN Biostatistics Center answered a wide range of questions. At the end of the afternoon, RAs were encouraged to become involved in one of the RA subcommittees. Approximately 13 RAs joined this session to learn more about the four ACRIN RA subcommittees. (For RAs who could not attend this session, please see the RA subcommittee article in this issue.)

The day ended with a chance for RAs to mingle and network during the reception held in the ballroom. It was great to see everyone interested in sharing his or her time and talents throughout the entire day. We appreciate the feedback we received on the meeting evaluations. Please know that we will keep your comments in mind as we plan next

year's meeting. If you did not complete an evaluation and have any suggestions for future meetings, please email your suggestions to Lorna Beccaria at LornaB@ocsi.us.

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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Help for Trial Management

Many RAs have found helpful assistance in handling aspects of managing an ACRIN clinical trial by taking advantage of the ACRIN Operational Management Tool (fondly known as the "Ops Tool"). The tool provides Web-based access to real-time reports that can help make your RA responsibilities more manageable.

Currently, RAs can access the Participant Form Calendar module for site-specific information related to participant calendars. Reports can be generated that document forms or images that have been submitted (retrospective) as well as forms and images that are due (prospective) within a specific time period. Such reports can also be requested for a specific study or case number, or for all studies and case numbers.

A proponent of the Ops Tool, Ferdinand Osuagwu at UCLA reflects on the benefits of this resource:

"The research world is becoming more and more complex as the days go by. Field RAs grapple with lots of challenges with increased workload, multiple demands by the site PIs thus making the adherence to forms due date to be difficult sometimes."

Although we lack the ability to control how many hours we have in a day, we have to control how we spend the hours. Thus, prioritization becomes really crucial in order to meet the challenges demanded by our work. The Ops tool has helped immensely in identifying due forms, and the good thing about this is that

it gives me a quick snap shot of due forms. This helps me to focus on forms that are due for submission first before attending to other ones."

Accessing the Ops Tool will become even easier with the launching of the updated ACRIN Web site. A link on the site's home page will now lead users directly to the tool, where the ACRIN-assigned user name and password will be requested. Requiring selection of the 4-digit ACRIN institution number further protects and limits access to data pertaining to the user's institution only. Remember to take advantage of the extensive functions available through this tool and to be on the lookout for future upgrades in capability.

RA Toolbox

Wondering who to call at ACRIN Headquarters when questions come up in carrying out your responsibilities as an ACRIN research associate? Whether your questions involve the initial approval of your site, the submission of data, the acquiring and scanning of images, or the reporting of adverse events, ACRIN is committed to providing you with the tools you need to conduct your imaging research study effectively. Our goal is for you to reach the appropriate staff person to answer your question during your first call to ACRIN so that you can spend your limited time on other activities.

Toward this goal, the design of the new ACRIN Web site now provides access to protocol-specific staff contact information on the page for each ACRIN protocol. This list can be found under the Contact Personnel link under Protocol Specific Materials. We hope that making this information available in one place will help streamline your problem-solving efforts.

To further assist you in this process, we offer an overview of the support provided by ACRIN headquarters personnel.

Project Management

- Trial Participation Approval process
- Budget and site reimbursement
- Change in site personnel

Administration

- ACRIN reader ID assigned to the site PI or site reader
- User name request form for password
- Case-specific labels

Data Management

- Protocol and eligibility
- Form completion and submission
- Participant calendar (crediting)
- Forms due reports

Imaging

- Image acquisition and scanning
- Image QC
- Crediting of images to calendars

(NOTE: For information about the electronic submission of images, RAs should contact Triad-support@phila.acr.org)

Regulatory

- Questions about IRB approvals
- Notifying ACRIN of IRB approvals
- Questions regarding consent issues
- Questions about IRB approvals that require DSMB reports
- For questions on adverse events, consult the Regulatory Resources links on the home page of the specific protocol

(NOTE: Questions on reporting adverse events should be directed to the TRI-staffed 24-hour telephone number [301-897-1704]. Representatives are available M-F, 7:30 AM-7:30 PM ET. Leave a message after staffed hours.)

We hope these new tools help to enhance your experience as an ACRIN RA and welcome your feedback as you make use of them in your daily operations.

Join Fellow RAs Participating in Subcommittee Activities

Several RAs took advantage of the Fall Meeting to pursue more active participation within the various ACRIN RA subcommittees. Other RAs interested in serving in this worthwhile and career-enhancing capacity, can choose from the following membership opportunities:

Education

Lorna Beccaria, Chair

Continues its work on training new RAs and providing educational opportunities for all RAs, including information about professional certification (e.g. SoCRA, ACRP)

Mentoring

Tracy Petro, Chair

Putting processes in place that will allow experienced RAs to reach out to new RAs with help and information

Networking/Communications

Lynn Werner, Chair

Continues to produce and deliver a quarterly RA newsletter and update the ACRIN RA Web site as needed

Quality Assurance

Cindy Cobb, Chair

Focusing on standardization of data forms, and testing data entry

Subcommittee members participate in quarterly conference calls and meet during the annual ACRIN Fall Meeting.

Interested in expanding your RA horizons this year? Log onto the ACRIN Web site and access the RA Committee section. Complete the RA Subcommittee Questionnaire and submit it, along with your CV, to ACRIN. The chair of the subcommittee in which you've expressed interest will contact you regarding ways in which you can contribute to the subcommittee.



DMIST RAs gather to reminisce.



Networking during the RA reception is an added bonus of attending the ACRIN Fall Meeting.



Barbara LeStage, MPH, Liz Morrell, RT (R), Lynn Werner, RN, CCRC, and Mark Rosen, MD were four of the 2007 Outstanding Achievement Award recipients.

ACRIN Acronyms

Ever wonder about the meaning of all those acronyms that are being thrown at you on conference calls and ACRIN meetings? Well here is a list that can help you understand what all those arbitrary terms stand for:

<u>AIM</u>	Image Annotation Markup
<u>CaBig</u>	Cancer Biomedical Informatics Grid
<u>CRA</u>	Clinical Research Associate
<u>CT</u>	Computed Tomography
<u>CTEP</u>	Cancer Therapy Evaluation Program
<u>DM</u>	Data Management
<u>DWI</u>	Diffusion Weighted Imaging
<u>MRI</u>	Magnetic Resonance Imaging
<u>MRSI</u>	Magnetic Resonance Spectroscopic Imaging
<u>MRS</u>	Magnetic Resonance Spectroscopy - another term for MRSI
<u>NCIA</u>	National Cancer Imaging Archive
<u>NCI LSS</u>	National Cancer Institute Lung Screening Study
<u>PBTC</u>	Pedi Brain Tumor Consortium
<u>PET</u>	Positron Emission Tomography
<u>RA</u>	Research Associate
<u>RC</u>	Research Coordinator
<u>VIEW</u>	Virtual Imaging Evaluation Workspace
<u>XIP</u>	Extensible Imaging Platform

For more acronyms and acronym resources visit the RA committee section of the new ACRIN Web site:

www.acrin.org/committees/RA Committee