

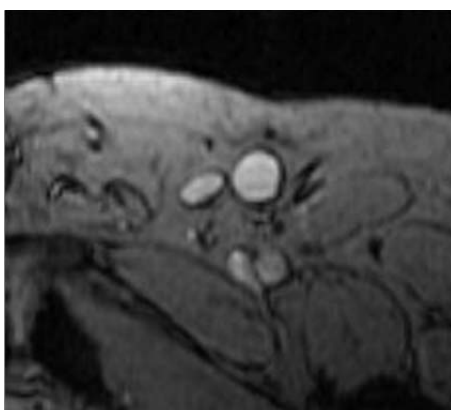
New Cervical Cancer Trial Enrolling Participants

A new ACRIN-GOG collaborative trial offers an opportunity for RAs to participate in innovative research designed to improve the accuracy of diagnosis and treatment planning for the thousands of women diagnosed annually with cervical cancer. GOG 0233/ACRIN 6671 investigates whether PET/CT and MRI using an investigational contrast agent can identify lymph node metastasis in patients with locoregionally advanced disease. Studies in other types of cancer have demonstrated impressive sensitivity and specificity for PET/CT and MRI. This, however, is the first study comparing the ability of the two modalities to detect metastasis cervical cancer. Traditionally, staging has been determined on a clinical basis. Successful use of imaging for this purpose would reduce the potential long-term side effects connected with invasive surgical dissection and increase the accuracy of disease staging, allowing for more

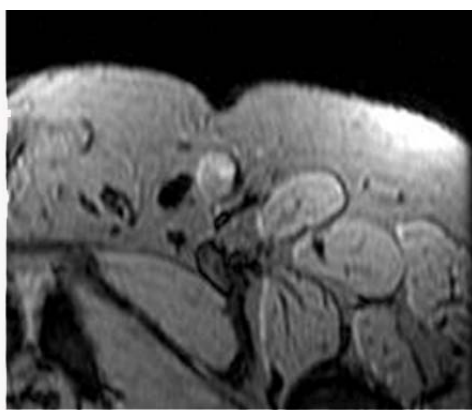
patient-tailored treatment decisions. Consult the sidebar on page 3 for additional online information about cervical cancer.

Participants are accepted for enrollment in the trial following a histological diagnosis of locoregionally advanced cervical cancer and before chemoradiation treatment is initiated. They undergo PET/CT scanning and subsequently receive an injection of the contrast agent ferumoxtran-10 (Combidex). Made of superparamagnetic iron oxide nanoparticles, this agent accumulates and appears as darkening in normal lymph nodes and allows lighter-appearing metastatic nodes to be more easily identified about 24-36 hours following administration. An MRI scan is conducted during this time period. Participants then undergo extraperitoneal or laparoscopic pelvic and abdominal lymph node dissection, aimed at pathologic verification

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Pre-contrast



Post-contrast

Precontrast image shows two hyperintense lymph nodes in the left inguinal region. 24 hours after the administration of ferumoxtran-10, the medial node shows homogenous uptake and is consistent with benign etiology. The lateral node continues to stay hyperintense with some faint peripheral uptake which is suggestive of malignant infiltration, which was proven by histopathology

Fall Meeting Preview

Save the Date!!

Please mark your calendar for the day-long RA Symposium at the 2008 ACRIN Fall Meeting on Thursday, October 2 at the Ritz-Carlton, Pentagon City, in Arlington, VA.

The Research Associate Executive Committee members met at the ACRIN Spring Meeting to plan a day packed with information of importance to all RAs. The theme of this year's meeting is "developing relationships." Activities planned for the symposium include guest speakers, a panel discussion, a boot camp for new RAs, and workshops on accrual, retention, follow-up, and adverse events collection and reporting. Some fun-filled activities are also in store.

A luncheon is a traditional part of the day, along with the Thursday evening reception so that we can mingle with new and catch up with longtime friends.

See you in October!

Don't Miss Inside

The SoCRA certification exam will be offered in conjunction with the Fall Meeting - details on page 2.

The deadline for submission for the 2008 Jo-Ann D'Amato Award of Excellence is June 13. See information on page 5.

Spring Meeting Report

The RA Executive Committee members met at the ACRIN Spring Meeting, held this year in sunny Coronado, CA on March 19th and 20th, to plan our activities for 2008.

Day 1

We started by setting our deadlines for the announcement of and application for the 3rd annual JoAnn D'Amato Award of Excellence. You should have received a broadcast e-mail announcing the request for applications. If you have not received it, please contact Danielle Hunter at ACRIN headquarters (dhunter@phila.acr.org) to make sure you're on our distribution list. This newsletter also includes an article on the award; please look for it and submit a nomination.

We continued our day by meeting with ACRIN leadership. We had a chance to talk with Mitch Schnall, MD, ACRIN's Study Chair, and Charlie Apgar, ACRIN Administrator. Maria Oh and Nancy Fredericks from ACRIN also joined us for the discussion. We talked about our activities to date and plans for the future. The RA Executive Committee once again plans to survey ACRIN RAs about their education, salary scales, experience, etc, so that we can complete our second paper for publication. Keep an eye out for the RA survey to appear in your e-mail in the next couple of months.

We spent the remainder of day one working with Maria Oh, Nancy Fredericks, Pam Harvey, and Tina Taylor on the educational tool that will soon be available for new RAs. This will consist of a series of slides that new RAs will be required to review and be tested on, to establish a baseline level of understanding, before participating in any ACRIN trials

Day 2

Our work began with planning for the ACRIN Fall Meeting, including the RA session on Thursday, October 2, 2008 at the Ritz-Carlton, Pentagon City, in Arlington, VA. We have used the feedback received in the evaluation forms from last fall, and suggestions directly from you, to set up an information-packed session. Please put this day-long meeting on your calendar and look for a meeting announcement in July-we hope to see you there!



The RA Executive Committee held a two-day working session at the ACRIN Spring Meeting. Pictured from left to right are Tracy Petro, Lorna Beccaria, Wendy Smith, Pam Harvey, Cindy Cobb, Tina Taylor, Roz Marzan and Lynn Werner.

SoCRA Certification Exam Offered

The RA Executive Committee is pleased to announce that ACRIN, in cooperation with The Society of Clinical Research Associates (SoCRA), is hosting a **Clinical Research Professional Certification Exam** for ACRIN and other RAs. The examination will be offered in conjunction with the ACRIN Fall Meeting.

SoCRA, a professional membership organization, was developed to provide educational programs, certification, and a forum for research professionals to exchange information. Please visit the SoCRA Web site (www.socra.org) for further information about joining the organization, eligibility for the exam, and online exam registration.

SoCRA Certification Exam Information

Date: October 1, 2008

Time: 2:00-7:00 PM

Location: Diplomat Room
Ritz Carlton, Pentagon City,
Arlington, VA

Associated Cost:

Membership Application Fee:
\$75 (U.S.) per year

Certification Application Fee:
\$195 (U.S.)

Cervical Cancer Trial

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of the nodal status. A 40-participant subset agreeing to take part in an optional arm undergoes an additional MRI before the injection of Combidex in order to validate the similarity of nodal size identified with and without the contrast agent. The trial involves a central reader study in which seven expert readers evaluate the diagnostic sensitivity and specificity of the two imaging modalities.

The structure of GOG 0233/ACRIN 6671 requires that participants be identified and recruited by the research staff of the gynecologist surgeons at GOG member institutions. ACRIN RAs will find that developing and maintaining a relationship with these GOG RAs will go a long way toward achieving successful recruitment levels. This could involve regular contact to discuss how recruitment is going, to identify potential par-

ticipants in their schedule, and to offer assistance with the patient consent process. In the case of GOG RAs busy with many research projects, such contact can also keep this trial a top priority in their minds.

GOG 0233/ACRIN 6671, activated in September 2007 with a target accrual of 325 participants, is currently being conducted in six sites. Investigators interested in participating in the trial can access a wealth of documents from the Protocol Summary Table of the newly enhanced ACRIN Web site, including protocol-specific applications, recruitment brochures, imaging guidelines, ACRIN contact personnel, and protocol management manuals. For more information, contact Heather Polley (hpolley@phila.acr.org; 215-717-0936) protocol manager for the ACRIN 6671 trial.

ACRIN 6671 RA Lena Marra Offers Strategies for Fostering Relationships with GOG Staff

Lena Marra is enthusiastic about her role as an ACRIN RA at Mt. Sinai Hospital supporting the ACRIN 6671/GOG 0233 trial. Through her new role, she is now more aware of the extent of cancer in her community, and is grateful to be offering innovative treatment for cancer patients.

To initiate dialogue with the GOG PI and RA, Lena and the ACRIN PI scheduled a meeting to clarify their respective procedural systems and discuss protocol issues that might arise. Because of the study's imaging time frames, she says, "we wanted to have everyone on board and ready before patients were enrolled. It may be necessary to meet several more times to develop ongoing strategies for working together." Issues related to the transfer of medical records and precertification of insurance coverage for PET also made it necessary for Lena to initiate

communication with other hospital departments.

Several times a week, Lena calls the GOG RA to see if any new patients have been identified who might be eligible for the study. According to Lena, such frequent contact is necessary for planning purposes because "things need to happen quickly once the patient is enrolled." When her schedule allows, Lena visits the physician's office to pick up medical records or to help with having an eligible patient sign consent forms. She emphasizes the importance of having a signed copy of the consent before the patient has any of the imaging exams.

Once a participant is enrolled, Lena finds that e-mail communication is best for following up on the various study requirements, including staging of the cancer and scheduling of imaging appointments. Lena also highlights the

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Links for Cervical Cancer Information

The following organizations provide substantial content related to cervical cancer on their Web sites. We hope you find them helpful, both in managing this protocol and in providing resources for the participants enrolled.

1. National Cancer Institute

www.cancer.gov/cancerinfo/pdq/treatment/cervical/patient/

2. American Cancer Society

www.cancer.org/docroot/LRN/LRN_0.asp?dt=8

3. National Women's Health Resource Center

www.healthywomen.org/Page.do?pageCode=healthcenter-cervicalcancer

4. National Cervical Cancer Public Education Campaign

www.cervicalcancercampaign.org

5. National Cervical Cancer Coalition

www.nccc-online.org

6. Women's Cancer Network / Cervical cancer information

www.wcn.org/interior.cfm?diseseid=3&featureid=1

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

**American College of Radiology
Imaging Network
Administrative Headquarters
1818 Market Street
Suite 1600
Philadelphia, PA 19103**

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Adverse Event Reporting Overview

Adverse event (AE) reporting can be challenging, especially when reporting systems undergo changes. However, proper documentation of AEs within the participant's study chart and their timely reporting to the appropriate entities is critical for effective trial management. ACRIN's AE Coordinator, Cornelia (Lia) Tsikos, at 215-574-3236 or ctsikos@phila.acr.org, is available to address AE-related questions.

To aid accurately reporting AEs to ACRIN and other regulatory bodies, it is important to review the protocol-specific reporting process in the AE section of each protocol. Also, the ACRIN Adverse Events Log is a tool sites can use as a source document. It is designed to capture all pertinent participant data and to allow for a quick assessment of AE reporting appropriateness. This document is available under the new Regulatory Resources page on the ACRIN Web site at www.acrin.org, where users can also find an updated AE Information Sheet and other important resource documents. When reporting AEs to the National Cancer Institute (NCI), note that the expedited reporting process, previously handled by the NCI's Cancer Imaging Program (NCI/CIP), has

been transitioned to Technical Resources International, Inc. (TRI). The study-specific details of the updated expedited reporting process are described in each protocol. For assistance completing an AdEERS report, contact TRI through the AdEERSMD help line at 301-897-7497. The ACRIN AE Manual, currently being revised to clarify and include details of the TRI expedited reporting process, will be posted to the Regulatory Resources page as soon as it is completed.

ACRIN 6671 Interview

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need to support the participants, some who travel long distances to be take part in the study, by answering any study related questions and keeping them comfortable as they wait for their imaging appointments.

What would Lena recommend to other ACRIN RAs who want to develop a collaborative relationship with GOG RA staff? Without hesitation, Lena replies, "Meet with the GOG RA and PI, discuss how you can be of assistance to them, and open up the lines of communication to make the study operate as smoothly as possible."

Contribution Request for Annual RA Award

ACRIN RA Executive Committee members invite persons associated with ACRIN to consider a tax deductible contribution to the Jo-Ann D'Amato Award of Excellence. The annual award was established to honor an ACRIN research associate who carries out his or her work with the same commitment to excellence demonstrated by our beloved colleague Jo-Ann.

Contributions, maintained by the ACR, will fund the purchase of an annual recipient award and creation of an engraved plate to be added to a wall plaque displayed at ACRIN headquarters.

Please make your check out to ACR -- Jo-Ann D'Amato Award and send to the below address.

American College of Radiology
Jo-Ann D'Amato Award of Excellence
1818 Market Street, 16th Floor
Philadelphia, PA 19103

Thank you for your support,
The RA Executive Committee

RA Subcommittees

If you are interested in expanding your research associate horizons, 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 about their committee activities and what might be of interest to you.

Education

Lorna Beccaria, Chair
lornab@ocsi.us

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

Mentoring

Tracy Petro, Chair
Sitton-Petro.Tracy@mhsil.com

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

Networking/Communications

Lynn Werner, Chair
lynn.werner@uphs.upenn.edu

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

Quality Assurance

Cindy Cobb, Chair
ccobb@lifespan.org

Focusing on standardization of data forms, and testing data entry

Wishing you a fun-filled summer. . .see you at the ACRIN Fall Meeting!

Request for Nominations

The ACRIN RA Executive Committee requests nominations for the third 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.

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

Application and instructions for submission can be found on the ACRIN Web site: www.acrin.org. Go to "Committees", "Research Associates", and "Materials".

Nominations must be received or postmarked by Friday, June 13, 2008.

The award presentation will be at the ACRIN Fall Meeting, October 2008.