A Tip from the Mentors

When coordinating research with referring physicians, keep updated copies of the protocol and consent forms in a location in their office setting. This cuts down on the amount of materials you need to transport to consent patients and serves as a resource to the physician and office staff if questions arise regarding the protocol or consent.

Save the Date:

The 2009 ACRIN Fall Meeting will be held September 30 through October 3 at the Ritz-Carlton Pentagon City, Arlington, VA. The Research Associates Education Session will again kick off the meeting on Wednesday, September 30th. Also, the Society for Clinical Research Associates (SoCRA) has decided to once again offer the SoCRA certification exam in conjunction with the meeting. More details to come.

ACRIN RA Tutorial Aids New Research Associates

Imagine that you’ve just been hired as a research associate (RA) to start up an ACRIN trial. This is your first foray into clinical research and you’ve never heard of ACRIN- much less know what the acronym means. You have your supplies, are connected to the hospital’s computer system, and have successfully found your way to the cafeteria. Now what?

Although many facilities have helpful support systems in place for new RAs, members of the ACRIN RA Executive Committee know how important it is for RAs in all settings to have access to resources for learning the essentials of managing an ACRIN clinical trial. Toward this goal, the committee embarked on the development of an "ACRIN RA Tutorial." Created in tandem with ACRIN staff members, the tutorial’s five modules provide information about ACRIN administrative operations, regulatory requirements, and data management procedures. Also presented is the unique role that imaging plays in an ACRIN trial along with information about the many support activities offered by the ACRIN RA Committee.

To help ensure that they have a solid understanding of ACRIN clinical trial basics, all new RAs are required to review the online tutorial and complete an associated quiz before obtaining an ACRIN username and password. These identifiers are required to gain access to the Data Management Center and to enter clinical data into ACRIN’s electronic Web forms. Links to the tutorial PDF document and the electronic quiz are available in the RA Committee section of the ACRIN Web site at: www.acrin.org/RA_Tutorial.aspx

Once an RA has reviewed the tutorial, taken the quiz, and submitted the "Username and Password Form" (accessible through instructions in the tutorial), he or she will receive e-mail notification of the assigned username and password. The quiz answer key, included in the same e-mail, will allow the RA to then correct his or her quiz. In addition, the names of

(continued on page 5)
ACRIN 6678, led by Wolfgang Weber, MD, is a multicenter clinical trial evaluating a patient’s response to treatment with positron emission tomography (PET). This study is unique as one of the first clinical trials supported by the Biomarker Consortium, a public-private biomedical research partnership launched in 2006 to search for and validate new biomarkers to accelerate the competitive delivery of successful new technologies, medicines, and therapies for cancer prevention, early detection, diagnosis, and treatment. Given its mission, the Biomarker Consortium looked to ACRIN to quickly enroll participants on to the ACRIN 6678 trial (at a minimum rate of 7 to 10 patients per month) in order to obtain data and provide answers to this study's proposed research questions.

Concern over sluggish trial accrual after the trial was well underway led ACRIN to survey RAs at participating centers in order to better understand the barriers to enrolling participants and to modify the study design to boost accrual. The survey was carried out through the use of screening logs on which the RAs recorded why potential study participants were, or were not, enrolled in the study. The information gathered from this tool was extremely helpful for developing protocol amendments aimed at maintaining the current study objectives while alleviating significant accrual barriers to the extent possible.

In addition, the RAs at each site coordinated conference calls that brought together all of the clinicians and support personnel responsible for carrying out the trial. Coordinating a call to accommodate everyone's schedule was often a challenge. However, the information gathered from the conversation among the site personnel and ACRIN trial leadership also played an important role in confirming how to alter the research design to accommodate improved accrual.

A document highlighting the key protocol revisions is available on the ACRIN Web site at www.acrin.org/6678_protocol.aspx (Under "Protocol Specific Materials" select "Site Memos". The "Protocol Changes Memo" appears under "Administrative Memos".)

Thank you to all the RAs who supported this effort and continue to carry out strategies to expedite enrollment for this important trial.

“A special thank you goes to the research associates who took the time to inform us about accrual obstacles through the screening logs. What we learned had a significant impact on the trial redesign.”

Wolfgang Weber, MD
ACRIN 6678 Principal Investigator

Seeking Contributions to the RA Newsletter

The ACRIN Research Associate Newsletter provides a means to keep in touch with one another. To improve that process, we are requesting information from each of you that can be shared. The contribution can be a few lines or an article written by you. If the resource is properly cited, we can also re-print information from other sources. Please forward all contributions by email to lynn.werner@uphs.upenn.edu for review by the RA Executive Committee. We look forward to hearing from everyone. Here are a few suggestions:

- Day in the life of an ACRIN Research Associate
- Human interest story (no names please)
- New technology
- Recruitment challenges and difficulties
- Ideas to boost recruitment
- Ideas to facilitate retention
- Helpful tips, shortcuts, and suggestions

Topics are not limited to these suggestions. Be creative!
Research Associates Develop Relationships at ACRIN Fall Meeting

The 9th annual RA session was held on October 2, 2008 at the Ritz Carlton-Pentagon City in Arlington, Virginia. Approximately 100 attendees participated in this highly successful event.

Large-Group Sessions

In keeping with this year’s theme of "Developing Relationships," representatives from several other cooperative groups began the day by highlighting their organization, research, and ideas for working together to further our research efforts. The RAs in attendance responded positively to each of these opportunities for sharing ideas and information. This should be the springboard for future collaborations with each of these groups. RA subcommittee members Lena Marra, Ferdnand Osuagwu, and Suzanne Lenz ended the morning with short presentations and a panel discussion focusing on their experiences in accrual, staff relations, and follow-up.

After lunch, the RAs attended one of two enlightening programs:

- **RA Boot Camp**, organized and presented by the RA mentoring subcommittee, to provide research basics to those just starting out on ACRIN trials. Similar future sessions are planned due to positive feedback from attendees.

  - **"Communicating in a Digital World"** by Hank Brasteter, director of ACRIN management information systems. This entertaining and informative update was attended by "long-timers" (experienced RAs).

The groups then came back together for two presentations. First, representatives from the National Cancer Institute (NCI) enlightened the audience about the newest information on adverse event reporting and the new electronic AdEERS pathway. Second, representatives from the patient advocacy and special populations groups shared their thoughts on reaching out to the community and community resources available to help us with recruitment.

Break-out Sessions and Networking

This year, roundtable discussions again afforded RAs an opportunity to ask questions and discuss issues related to specific protocols in an informal venue. Representatives from ACRIN project managers, data management, imaging, and regulatory provided a broad range of expertise to these sessions.

Approximately thirteen RAs also participated in a session to learn more about the four ACRIN RA subcommittees and how becoming involved can help enhance the research study experience of all ACRIN RAs.

The day ended with a chance for all of the RAs to mingle and network during the reception. It was indeed a day of "developing relationships" in which all participants abundantly shared their time and talents. The feedback received on the meeting evaluations is appreciated and will be helpful for planning next year's meeting. Additional suggestions for future meetings can always be e-mailed to Lorna Beccaria (LornaB@ocsi.us).

RA Subcommittees Participation

If you are considering stepping up to this rewarding opportunity, please complete the "ACRIN RA Subcommitte Questionnaire" available on the ACRIN Web site: www.acrin.org/RA_Materials.aspx and forward it to Tina Taylor (ttaylor@phila.acr.org).

Your responses will assist ACRIN in matching your experience, training, and areas of interest with appropriate subcommittee activities.
More Acronyms

If you attended the 2008 ACRIN Fall Meeting, you may have experienced acronym overload. The following list may help!

CTSA: Cancer Trials Support Unit
CTIS: Clinical Trials Information System
CIP: Cancer Imaging Program
AdEERS: AE Expedited Reporting System
DCTD: Division of Cancer Treatment and Diagnosis
CFR: Code of Federal Regulations
OHRP: Office of Human Research Protections
CMS: Centers for Medicaid and Medicare Services
OCR: Office of Civil Rights
TRI: Technical Resources International
MM: Medical Monitor
CTC: Common Toxicity Criteria
IDE: Investigational Device Exemption

The above acronyms will be added to a more comprehensive list available at www.acrin.org/RA_Materials.aspx

Research Associate Collaboration in the Radiation Therapy Oncology Group

As in ACRIN clinical trials, research associates (RAs) play an important role in the studies conducted by other national clinical cooperative groups, many of which have established separate committees focusing on issues of concern to RAs carrying out their research. One such cooperative group, the Radiation Therapy Oncology Group (RTOG), was organized in 1968 under the direction of Dr. Simon Kramer for the purpose of conducting radiation therapy research and cooperative clinical investigations. RTOG began receiving National Cancer Institute (NCI) funding in 1971, and its initial study of adjuvant methotrexate in advanced head and neck cancer was considered a milestone in multidisciplinary research. More information about RTOG, including its objectives, membership categories, and committee activities, can be obtained by visiting the RTOG Web site at www.rtog.org.

RTOG RA Committee Mission and Leadership

The mission of the RTOG RA Committee, formed in 1984, is to include an RA member in each committee of the RTOG to represent the RA’s perspective as well as to act as a liaison between the RTOG committee and the RA Committee to facilitate the conduct of studies.

The leadership of the RTOG RA Committee includes the chair, co-chair, secretary, and membership chair. The chair presides over the RA Steering Committee and the RA Committee and meetings. The co-chair assists the chair with conduct of meetings, and functions as the chair in his or her absence. The secretary records minutes of meetings, while the membership chair maintains a database of RA Committee members with contact information.

The RTOG RA Committee is open to every RTOG RA, and new committee members are always welcome.

Components of the RTOG RA Committee

Existing subcommittees focus on the content areas described below.

(continued on page 5)
RA Education Committee - The Education Committee plans and develops the RA panel discussion and RA scientific session at the RTOG semiannual meeting. Members of this committee determine the subject matter of these two programs based on needs assessment, recruit speakers, and apply for continuing education (CE) credits for nurses and RAs. The chair and co-chair of the committee introduce the speakers and moderate the programs. The Education Committee members collect evaluation forms and distribute CE certificates.

RA Research Strategy Committee - The Research Strategy Committee was formed to offer RAs the opportunity and forum to conduct clinical research and be a principal investigator. In this committee, RAs develop concepts for supportive care or intervention protocols. The first RA protocol using Biafine® cream in breast cancer patients receiving radiotherapy was published and presented at the American Society of Therapeutic Radiation Oncology (ASTRO) meeting in 2005. Another protocol using Biafine cream in head and neck cancer patients receiving radiotherapy was published in 2006. The RA Research Strategy Committee has two concepts currently in development: acidophilus to reduce thrush in head and neck cancer patients receiving radiotherapy and Linde serum for cetuximab-induced rash.

RA Disease/Discipline Committee - Members of the Disease/Discipline Committee are assigned to the Disease Site Committees and working groups to represent the concerns of RAs at RTOG meetings. Protocols in development are reviewed by the RA assigned to determine feasibility of the study and its conduct in RTOG institutions. An acuity tool, developed by this committee to determine the complexity of each trial reviewed, has been validated but not yet published for use by other groups.

An RA sits as a member of the RTOG Quality Control Committee, which discusses areas of deficiencies found at the time of audit. This member reports concerns of quality control regarding deficiencies to the RA Committee. He or she also meets with the Education Committee, which develops programs to educate RAs in ways to prevent deficiencies and improve data quality.

RA Poster Contest Committee - RAs are invited to participate in the poster contest held at the summer RTOG meeting. The Poster Contest Committee recruits poster presenters and coordinates the contest. Posters are displayed in a central area at the meeting where judges score the posters and determine a winner. The winner is announced at the RTOG business meeting and awarded an $800 travel voucher to any educational meeting.

RA Mentor Committee - The Mentor Committee was established by the RTOG Membership Evaluation Committee. Its purpose is to assist any institution receiving unacceptable Membership Evaluation scores (ie, less than 80%). Mentor Committee members assist institutions with audit preparation by cleaning up data, educating staff, helping the institutional principal investigator assess staffing levels, and developing action plans. Members are required to have five or more years of experience with a full member or affiliate member institution that enters 10 to 20 cases each year, acceptable data quality scores and site visits, and approval from their home institution and RTOG Headquarters data management staff and/or audit staff.

RA Communications Committee - The Communications Committee coordinates the publication of the RA Reporter newsletter. Members write articles and recruit writers to develop articles. They photograph events at the RTOG semiannual meetings for publication in the newsletter. The committee works with RTOG headquarters to publish the newsletter and post it on the RTOG Web site.

Headquarters Liaison - RTOG Headquarters assigns a representative to the RA Committee to serve as a liaison between the RA Committee and headquarters. This representative updates the RA Committee about activities at headquarters and takes concerns and questions of RAs to headquarters for resolution. The headquarters liaison offers educational opportunities to the Education Committee and the RA Committee as a whole.

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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