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The Research Associate Committee of the ACR Imaging Network

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Abstract

Research associates (RAs) play an important role in ensuring the quality of clinical trials. They are largely responsible for maintaining the accuracy and timeliness of data collected and for complying with applicable regulations. At the ACR Imaging Network (ACRIN), a cooperative group, RAs have formed a committee with the mission of helping ACRIN achieve its goal of conducting quality multi-institutional imaging clinical trials. Because of the varying backgrounds and levels of experience of ACRIN's RAs, one of the first goals of the committee was to develop an educational program that would provide standard training to all RAs. The committee also felt that RAs should be involved in the protocol development process from the earliest stages, and they are now represented on each major ACRIN committee. Other committee activities include publishing a newsletter, conducting an RA questionnaire, maintaining a Web page, and developing an online training tool. With hard work from the committee members, support from ACRIN's leadership, and demonstrated accomplishments, the committee has become an integral part of ACRIN's organization.

Keywords

Clinical trials; diagnostic imaging; research personnel; training

INTRODUCTION

Research associates (RAs also known as clinical research coordinators) play an important role in ensuring the quality of clinical trials. Research associates are largely responsible for guaranteeing that data are collected and reported in a timely fashion and that the data are accurate and correctly reflect patients' medical records; maintaining appropriate documentation; identifying study subjects; and making sure that all study procedures are performed in compliance with study protocol, hospital regulations, federal guidelines, and good clinical practice. With clinical research coming under increased scrutiny, the role of RAs is now even more important than in the past.

At the ACR Imaging Network (ACRIN), a National Cancer Institute-funded cooperative group, RAs have, with the encouragement of ACRIN's leadership, formed a committee that we believe has contributed to the success of the ACRIN organization.

ACRIN

ACRIN, one of the newest cooperative groups, was created in 1999 when Bruce J. Hillman, MD submitted a grant application in response to a request for applications to create a cooperative group to conduct imaging clinical trials. The grant was funded by the National Cancer Institute for approximately \$22 million for a 5-year period. ACRIN was founded on the unique premise that there would be no fixed member institutions but rather a flexible organizational structure that could respond quickly to new developments. ACRIN is composed of 3 main components: (1) ACRIN Headquarters, which is located at the main research offices of the ACR in Philadelphia and provides data, administrative, and financial management expertise; (2) the Biostatistical and Data Management Center, located at Brown University; and (3) a series of committees, including leadership, scientific, and support committees [1]. An organizational chart of ACRIN's structure, including the RA Committee, is shown in Figure 1. Since its inception, ACRIN has opened 15 clinical studies and has completed accrual for 7. This includes 2 large, nationally recognized screening studies, ACRIN 6652 and 6654, with 49,520 and 18,893 participants, respectively. Currently, more than 76 institutions have participated in ACRIN's clinical trials. In 2004, the grant was renewed for an additional 4 years. More information about ACRIN can be found on its Web site at <http://www.acrin.org>.

PURPOSE AND DEVELOPMENT OF THE RA COMMITTEE

The RA Committee was conceived in 2000 by a small group of 6 RAs (the "core" committee members) who felt that increased RA participation in ACRIN's activities would enhance the quality of ACRIN's clinical trials. Five of the 6 founding members are from various institutions around the United States, and 1 is from ACRIN Headquarters. This group met informally during the 2000 semiannual meetings and decided to pursue the formation of an official committee, as has been done in other cooperative groups. The group prepared a written proposal outlining the goals for the committee, its structure, and its functions. The proposal was presented to ACRIN's leadership in February 2001 and was accepted shortly thereafter. With much to accomplish, the founding members held a special meeting at ACRIN Headquarters during the summer of 2001 to formulate an action plan for the committee in general and for the 2001 fall meeting in particular. The first major achievement of the committee was participation in the 2001 fall meeting.

A primary goal and the one the committee first concentrated on was to provide education in data management to all ACRIN RAs. Research associates are a diverse group, with varying educational backgrounds and levels of experience. This is evidenced by a recent survey of ACRIN RAs that revealed that they had a range of experience in data management from 2 months to 25 years and educational backgrounds ranging from high school diplomas to MDs. Before becoming RAs, they were nurses, radiologic technologists, medical secretaries, cancer registrars, billing personnel, and social workers. Only 11% had received certification through organizations such as the Society of Clinical Research Associates and the Association of Clinical Research Professionals. Most RAs (87% in our survey) learn their duties by on-the-job training. Therefore, it was felt to be important to provide structured training in various aspects of data management and to provide mentoring to RAs new to research and/or new to ACRIN.

The committee was organized into 4 subcommittees, addressing education, quality assurance, networking and communications, and mentoring, with one of the core members serving as the chairperson of each subcommittee. The original goal was for the core members to develop the

subcommittees, recruit new members, serve 2-year terms, and then hand over leadership to the new members. However, it was challenging to interest new RAs in serving in leadership roles, and the original core members are still serving on the committee as of December 2005. As ACRIN grew and the volume of work increased, the committee actively sought to recruit new members for the core committee, and 2 additional RAs joined the core committee in 2003.

Currently, the RA Committee functions as do the other ACRIN committees and is required to hold conference calls, meet in person at the semiannual and annual meetings, and submit an annual report to ACRIN's chairperson. In addition, ACRIN provides travel funds to the semiannual meetings for the RA Committee members, as with the other committees.

ACTIVITIES OF THE RA COMMITTEE

Educational Sessions

Because the educational component was considered to be the most important and one that would help fulfill ACRIN's goal of providing enhanced training to study personnel [2], the committee focused almost entirely in the early years on developing this program. Although the ACRIN Headquarters staff provided a basic training session during the semiannual meetings, the RA Committee members believed that these sessions could be enhanced, and oversight of these educational sessions was transferred to the RA Committee in 2002. The RA Committee made several major changes to the format of the educational sessions, the most important of which was to hold the sessions the day before the official meeting began and dedicate the entire day to the session. This allowed RAs to attend who might not otherwise be able to participate because of conflicts with other sessions. A format was developed that mixed the basic training provided by ACRIN with guest speakers lecturing on various up-to-date topics, roundtable discussion sessions, and lectures on ACRIN activities such as new protocols and the audit program. Between 2002 and 2004, attendance at the educational sessions averaged 85 RAs, with a range of 80 to 87. The agendas for the last 2 educational sessions are listed in Table 1.

The core committee believed that it was important for the site RAs to get to know one another and network and therefore arranged for lunch to be provided during the education session day. A reception for RAs followed the session for additional networking opportunities.

Another important development in the educational program was to provide continuing education credits for nurses, radiologic technologists, and RAs certified by the Association of Clinical Research Professionals and the Society of Clinical Research Associates. The committee anticipated that providing this incentive would encourage attendance.

Participant evaluations provided welcome feedback, and the results were carefully reviewed by the core committee members after each meeting. Future sessions were revised in response to this feedback. For example, a number of respondents felt that the overall length of the session was excessive (from 9:30 AM to 6:00 PM), and the next year's session was therefore shortened. The roundtable sessions proved to be popular, but with feedback that not enough time was allotted for each roundtable. For the following year's roundtable sessions, participants were allowed to remain at a particular roundtable as long as they wished, rather than having to rotate to a new table every 20 minutes. The committee will continue to refine the sessions on the basis of participants' feedback.

Overall, attendees were pleased with the RA sessions. Attendees were asked to rate various aspects of the sessions (the overall relevance of the conference, the amount of information presented, roundtables, opportunities to ask questions, the amount of time for networking, facilities, and session materials) on a 5-point scale of "poor," "fair," "good," "very good," and "excellent." From 66% to 80% rated various aspects of the sessions as "good" or "excellent,"

and only 0% to 9% rated them “fair” or “poor.” Figure 2 shows the overall rating from the 2004 educational sessions.

ACRIN Committee Participation

It soon became apparent to the core committee that ACRIN would benefit from RAs becoming included in the process of protocol development. Because RAs are often more involved in the day-to-day activities of carrying out clinical trials than physician investigators, they can contribute a unique perspective on developing a successful protocol. For example, principal investigators often underestimate the workload involved in a study or may not always understand the intricacies of completing case report forms or data entry processes, of which RAs are intimately aware. Therefore, in 2003, the RA Committee received permission from ACRIN’s leadership to have RA representation on each of the main ACRIN committees. In this way, RAs are involved from the very early stages of developing a protocol. The RA Committee chairperson became a member of the ACRIN Steering Committee.

Newsletters

In conjunction with ACRIN Headquarters staff members, the RA Committee publishes a semiannual newsletter for the purpose of keeping RAs abreast of the latest developments at ACRIN and other topics of relevance. Topics have included changes in headquarters staff, protocol updates, timely subjects such as Health Insurance Portability and Accountability Act regulations, information on upcoming annual meetings, adverse event reporting, the audit process, and an “Ask ACRIN” column. Always included is how to contact the core committee members and ACRIN staff members. Newsletters are e-mailed to all RAs and are also published on the RA Committee’s Web page.

ACRIN RA Committee on the Web

In keeping with the objective of open communication with ACRIN RAs, the RA Committee has established a Web page. This page can be found as a link on ACRIN’s main Web site or at <http://www.acrin.org/racommittee.html>. The page contains the committee’s mission statement, contact information for the core committee members, past newsletters, RA educational session agendas, and slides of selected educational session presentations. We anticipate that the Web site will be expanded in the near future to include a list of mentors by geographic location and area of expertise. Currently, the RA Committee is the only ACRIN committee with its own Web page.

RA Questionnaire

In 2004, the RA Committee decided to conduct a survey to understand the demographics of ACRIN RAs, learn their needs and concerns, and solicit ideas for future educational sessions. The survey was distributed at the 2004 spring meeting and was also made available on ACRIN’s Web site. The results were tabulated and presented at the fall 2004 RA educational session. Questions on the survey included items such as RAs’ backgrounds and training, certifications received, salaries, types of employment (full-time or part-time), difficulties with their RA jobs or with ACRIN, and workload. The survey was reissued in spring 2005 and presented at the fall 2005 meeting.

Philips Training Tool

As part of the committee’s goal to provide basic standardized training for all ACRIN RAs, the RA Committee is working closely with Philips Medical Systems (Koninklijke Philips Electronics N.V., Eindhoven, the Netherlands) to develop an online training tool. Philips envisioned a need for the web-based training of imaging professionals and created the Philips Online Learning Center to fulfill this need. The tool is completely customizable and is currently

used by a number of organizations and institutions, such as the American Society of Radiologic Technologists, Emory University, and ACRIN [3]. The tool can be accessed through a link on ACRIN's Web site or at <http://theonlinelearningcenter.com>.

The tool will consist of 6 modules, including ACRIN's policies and procedures, auditing, regulation, good clinical practice, human subjects training (via a link to the National Institutes of Health educational course Web site), and adverse event reporting. Each module consists of a series of educational slides and a posttest. Once the tool is fully developed, all new ACRIN RAs will be required to take and pass the modules before they will be allowed to participate in ACRIN studies. The online system is beneficial because RAs will not have to wait for the semiannual meetings to be trained, and because this minimum level of training will occur online, the ACRIN meetings do not need to repeat the training and can concentrate on newer or more advanced topics.

PITFALLS AND LESSONS LEARNED

Although we feel that the RA Committee has been successful in its primary mission of helping ensure the quality of ACRIN's clinical trials, there were obstacles to be overcome. For any committee to succeed, it needs the support of the organizational leadership. Many investigators consider RAs to be "support staff," and lobbying efforts were needed to convince ACRIN's leadership that RAs have contributions important enough to warrant involvement in ACRIN at the highest levels. With much hard work from the core committee members and demonstrated accomplishments, we now feel that RAs and the RA Committee are a respected part of the ACRIN organization. This is evidenced by recognition of a number of RAs who have been awarded ACRIN's Certificate of Outstanding Contribution. At each semiannual meeting, the network chair and ACRIN's National Cancer Institute representative present these awards during a luncheon ceremony. In 2003, 4 RAs received awards, and 2 of these were awarded to members of the RA Committee. In 2004, 3 RAs received awards.

As mentioned previously, it was the goal of the core committee members to serve for 2 years while developing the committee and subcommittees, then turn leadership over to new members. This goal proved to be challenging, because we were unable to recruit new members who were interested in this undertaking. At that time, ACRIN was relatively new, with a limited number of participating institutions and therefore a limited number of RAs. In addition, many were new RAs or new to the cooperative group mechanism and possibly did not feel qualified to participate. With ACRIN's growth (52 institutions participating in 2004 compared with 27 in 2001), the core committee has been contacted by a number of RAs who have expressed interest in joining the committee and serving on the subcommittees. With the increased personnel, we anticipate that all the subcommittees will be able to move forward.

FUTURE DIRECTIONS

Subcommittee Development

As mentioned earlier, with more RAs willing to join the committee, the full development of the subcommittees can be accomplished. With the exception of the Education Subcommittee, the other subcommittees have not been fully implemented. The primary vision of the Mentorship Subcommittee is to pair each new RA with an experienced RA to provide guidance and answer any questions the new RA may have. In addition, the committee will develop a list of experienced RAs who are willing to provide assistance in their areas of expertise, including modality-based (positron emission tomography, magnetic resonance imaging, interventional studies), disease site based, or regulatory (institutional review boards, regulatory documents, Health Insurance Portability and Accountability Act regulations). This list, with contact information, will be posted on ACRIN's Web site for all RAs to access.

The Networking and Communication Subcommittee has had several accomplishments, including the publication of the RA newsletter and the RA receptions. This subcommittee will work closely with the mentoring and education subcommittees to disseminate information originating from those subcommittee activities. This subcommittee will also develop a RA listserv to facilitate communication between RAs and between RAs and ACRIN staff members. Another goal of this subcommittee is to establish communication with external organizations to make ACRIN's name and mission known.

The primary goal of the Quality Assurance Subcommittee is to test case report forms before the start of a new study. Often, the authors of case report forms have become so involved in developing them that it becomes impossible to critically review them. Because RAs are the end users of case report forms and data entry programs, they are in a unique position to test them in a real-world environment. The Quality Assurance Subcommittee would pilot test the case report forms with several "real" cases from their own institutions, review them for consistency with the protocol, and then test the data entry process to ensure that the online database matches the paper forms. Two core committee members serve on the ACRIN Quality Assurance Committee, and any problems found would be reported to them for presentation to the Quality Assurance Committee.

RA Monitoring Support

To ensure valid clinical trials, image quality, data quality, and compliance with the written protocol, ACRIN's policies and procedures must be carefully maintained. The ACRIN Quality Assurance Committee and audit process are critical to quality assurance, and in addition, ACRIN has recently implemented a monitoring program to complement the Quality Assurance Committee and audit programs. Monitoring is commonly used for industry-sponsored protocols and consists of site visits from a sponsor representative beginning soon after study startup. This way, errors are caught and corrected early, eliminating many months of incorrect data being submitted. With ACRIN's limited budget, on-site monitoring is not possible, and ACRIN's monitoring program is done by mail. Case report forms and corresponding source documentation are mailed from the sites to ACRIN Headquarters for review. Although the RA Committee applauds this effort, the members also felt that in some cases, on-site visits should not be replaced. This would be the case with new institutions without track records, institutions that have had serious problems in the past, or those that through the audit process are found to have consistently substandard data quality. The RA Committee has proposed that volunteers from the committee travel to such sites to offer advice, training, and a corrective action plan, as appropriate. Although ACRIN would cover travel expenses, money would be saved because salary support would not be needed, and only selected sites would be visited. Regionalizing the monitors would save money on travel expenditures by having the RA volunteers travel to sites within a limited geographical area.

Using Technology

The RA Committee is committed to using technology to advance its mission. The first step to this end has already been taken, with the Philips training tool as described earlier. The committee plans to expand the modules within the tool to include specific training for each new protocol. The advantages include RA education at a time convenient to him or her, without waiting until the semiannual meetings to be trained. Cost savings should also be evidenced, because time would not be needed at the meetings for such training.

Presentations and Publications

The RA Committee believes that many RA contributions are important enough to warrant presentation at national or international meetings or publication in peer-reviewed journals. To this end, the committee has plans to submit for publication or presentation some of their more

important activities (with this publication being the first). Current plans include the Philips training tool and the RA survey results. In addition, the committee is considering implementing a special poster or oral presentation session during ACRIN's meetings to provide site RAs an opportunity to present their own work.

CONCLUSIONS

We feel that the RA Committee has played an important role in helping ensure the quality of ACRIN's clinical trials. The committee's primary accomplishment to date has been to organize the RA educational sessions held in conjunction with the semiannual meetings. By standardizing training for all RAs, ACRIN is assured of a minimum level of competency for RAs. With the support of ACRIN's leadership, RAs and the RA Committee are now an integral part of ACRIN's organization. The RA Committee members are dedicated to further development of the committee and continuing to help ACRIN meet its goals.

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Fig. 1.
American College of Radiology Imaging Network organizational chart showing the RA Committee (arrow).

Fig. 2. Results of 2004 educational session participant evaluation, overall rating by respondents (n = 65).

Table 1
Research Associates' (RAs) education session topics

Topic	Speaker(s)
Fall 2003	
Ethics in research	Guest speaker
Patient advocacy	ACRIN patient advocacy committee
ACRIN general review session (IRB/regulatory, protocol, networking, data management, on-site training)	ACRIN staff members
ACRIN audit review	ACRIN staff members
Imaging submission review	ACRIN staff members
Panel discussion: audit preparation	Site RAs
Roundtables (regulatory binder, audit, protocol specific, imaging, on-site training, ACRIN administration)	Core committee and ACRIN staff members
Fall 2004	
RA survey results	Core committee
Certification	Core committee
Philips tutorial introduction	Core committee
Patient advocacy committee update	ACRIN patient advocacy committee
Parent and family member concerns during the consent process	Guest speaker
Introduction to ACRIN Web site redesign	ACRIN staff members
Roundtables (ACRIN Web site, image transmission, study documents, regulatory binders and mentoring, audit, breast protocols, lung and radiofrequency ablation, ACRIN administration)	Core committee and ACRIN staff members
Conducting investigational clinical trials: FDA	Guest speaker
Are you truly informed about informed consent?	Guest speaker
QA Committee initiatives	ACRIN deputy chair

Note: ACRIN = ACR Imaging Network; FDA = US Food and Drug Administration; IRB = institutional review board; QA = quality assurance.