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A Survey of Clinical Research Coordinators in the Cooperative Group Setting of the American College of Radiology Imaging Network (ACRIN)

Wendy Smith, BS, RTRCV, CCRP, Sharon Salenius, MPH, Cynthia Cobb, BS, RTRCT, CCRP, Roslynn Marzan, BS, Sophia Sabina, MBA, Lorna Beccaria, BSN, CCRC, Tracy Sitton-Petro, AAS, CTR, CCRP, D. Lynn Werner, RN, CCRP, Monene Kamm, AS, CRC, Suzanne Lenz, MA, CCRP, and Tina Taylor

Rhode Island Hospital, 593 Eddy Street, Suite 17 Gerry House, Providence, RI 02903 (W.S., C.C.); 21st Century Oncology, Ft Myers, FL (S. Salenius); University of California, Los Angeles (R.M.); Fox Chase Cancer Center, Philadelphia, PA (S. Sabina); Hillblum Foundation, San Francisco, CA (L.B.); Clinical Radiologists, S.C., Springfield, IL (T.S.-P.); University of Pennsylvania, Philadelphia (D.L.W.); University of Cincinnati, Cincinnati, OH (M.K.); Dartmouth-Hitchcock Medical Center, Lebanon, NH (S.L.); American College of Radiology, Philadelphia, PA (T.T.)

Abstract

Rationale and Objectives—As one of the newest cooperative groups funded by the National Cancer Institute in 1999, the American College of Radiology Imaging Network (ACRIN) is interested in conducting successful clinical research programs and pursuing quality research. The ACRIN Research Associate (RA) committee was formed in 2000 and felt it important to better understand the demographics, duties, needs, and concerns of ACRIN RAs. Therefore, in 2008, the committee conducted a survey of ACRIN RAs regarding these issues.

Materials and Methods—The survey instrument consisted of 33 multiple choice questions covering demographics, salary, job satisfaction, work load, educational background, and training. RAs completed the survey electronically in June 2008.

Results—A total of 110 responses were received. All regions of the United States were represented. The years of experience and salary ranged widely from <1 year to 28 years and ≤ \$20,000 to ≥\$80,000 per year. The majority of respondents held at least a bachelor's degree, with many having previous health-related clinical training; only a small percentage of respondents having had formal training in research.

Conclusion—Our survey summarizes the demographics and educational background of the research associates within ACRIN. This may help administrators understand the needs and characteristics of RAs participating in cooperative group research. In today's environment with tight regulatory control, it may become necessary to improve educational standards or require certification through one of the professional research organizations.

Keywords

Research; coordinator; cooperative group; survey

Cooperative groups (CG) are major sponsors of oncology research in the United States, Canada, and Europe and enroll more than 22,000 patients onto clinical trials yearly (1). Most university-based programs include affiliation with at least one cooperative group and in many cases more than one. CGs are primarily funded by the National Institutes of Health using the cooperative agreement funding mechanism (U01 grants). The American College of Radiology Imaging Network (ACRIN) is one of the newest CGs, conceived in 1999, and funded by the National Cancer Institute. To date, ACRIN has opened 30 clinical studies and has enrolled more than 76,550 subjects (2).

Research Associates (RAs), also known as clinical research coordinators, play a critical role in supporting a successful clinical research program and ensuring the quality of research within the CG setting. RAs' responsibilities include preparing institutional review board submissions, maintaining regulatory documents, screening potential research participants, participating in the informed consent process, scheduling tests and treatments, completing and submitting case report forms, following the participants in accordance with protocol requirements, and ensuring compliance with hospital and federal regulations and Good Clinical Practice.

An ACRIN RA committee was formed within the organization in 2000. The main functions of this committee are to provide training and educational sessions to the RAs, represent RAs on other ACRIN Leadership and Scientific committees (eg, Steering, Quality Assurance and Experimental Imaging), enhance RA communication via a newsletter and website, enable mentoring to inexperienced RAs (3), and ensure the quality of research data. To help accomplish these tasks, the committee members felt it was important to better understand the demographics, duties, needs, and concerns of ACRIN RAs. Therefore, the committee surveyed ACRIN RAs in June 2008 regarding these issues. The results of the survey are reported here.

MATERIALS AND METHODS

The survey instrument consisted of 33 questions covering demographics, salary, job satisfaction, work load, educational background, and training (Table 1). Most of the questions were multiple choice for consistency purposes, but some were open-ended to elicit spontaneous responses. RAs completed the survey electronically.

Statistical analysis consisted of descriptive statistics, chi-squared tests, and *t*-tests, as appropriate. A *P* value of $\leq .05$ was considered to be statistically significant. All analyses were conducted using the SAS software package (SAS Institute, Cary, NC).

RESULTS

The electronic survey was sent to the email listing of RAs working on active ACRIN trials. A total of 110 responses were received. Not all respondents answered all questions.

Demographics

Of those RAs who responded to the survey, 86.2% were full-time employees. Sixty-four percent worked at a university hospital, 22% in a non-university setting, 6% in private practice, and 8% reported working at other types of institutions. All regions of the continental United States were represented, with 32% of RAs from the Northeast, 19% from the Southeast, 22% from the Midwest, 8% the Southwest, and 15% from the West. An additional 3% were from outside of the United States. Years experience as an RA varied widely, ranging from 0.1 to 28 years, with a mean of 8.6 years. Eighty-six percent of RAs

worked with other sponsors in addition to ACRIN (Fig 1). A mean of 37% of their time was spent on ACRIN activities (range, 0%–100%).

Salary

Salary was expressed as ranges in increments of \$10,000 (eg, <20,000, \$20,000–\$29,999, \$30,000–\$39,999). Because the question did not ask for an exact salary figure, we were unable to calculate the mean and median salaries. Salaries ranged from ≤\$30,000 to ≥\$80,000. The most common salary range reported was \$50,000–\$59,000, which was reported by 22% of RAs (Fig 2). RAs who supervised other employees had higher salaries ($P = .0002$ by chi-squared test; Fig 3), as did those with higher educational levels ($P = .0215$ by chi-squared test). Interestingly, salary was not significantly affected by full- or part-time status, type of institution, region of employment, or years of experience. Ten part-time RAs reported working 20–32 hours per week, with two-thirds of those working 30–32 hours per week. There was no statistically significant difference between the salaries of the full-time and part-time RAs ($P = .8012$ by chi-squared test). Of the full-time RAs, 18% earned <\$40,000, compared to 20% of the part-time RAs, 42% earned between \$40,000 and \$59,000 versus 30% of the part-timers, and 14% of full-time RAs earned >\$80,000 compared to 10% of part-time employees.

Background, Education, and Training

Fourteen percent of RAs held less than an associate degree (high school diploma, some college, or vocational/technical school), 21% had earned an associate's degree, 41% a bachelor's degree, 19% a master's degree, and 5% held a doctorate. Experience varied greatly, although most RAs indicated experience in a health-related field. Thirty-two percent had a nursing background, and 11% were radiologic technologists. RAs were questioned about what level of education they thought should be the minimal required to perform their job. Fifty percent reported that a bachelor's degree should be the minimum level, whereas 21% said an associate's degree, 17% certification, and 6% a high school diploma. There was a high level of correlation between whether an RA was certified and whether he or she thought certification should be required. Of the certified RAs, 73% thought certification should be a requirement, compared to only 21% of RAs who were not certified ($P < .0001$). Similarly, the educational level achieved by RAs correlated with their perception of what educational level should be required by RAs. Fifty-six percent of RAs who had less than a bachelor's degree felt that level was an appropriate level of education for RAs, compared to 18% of RAs who held a bachelor's degree and 7% of master-degreed RAs ($P < .0001$). Interestingly, only 18% of RAs who held a master's degree felt that a master's degree should be required of RAs, with most (74%) feeling that a bachelor's degree was sufficient.

In terms of training received for their ACRIN RA position, 94% indicated that they received on-the-job training. Thirty-one percent attended a training session, 14% had previous cooperative group experience, and 19% had previous noncooperative group experience. Nine percent were mentored by another institution's RA, and 9% reported having been trained via a degree program.

We asked the question, "How long did it take for you to feel comfortable in your position as a site RA?" RAs responded that it took a mean of 5.5 months (range, 1–36 months) to feel comfortable.

Certification

It was of interest to the RA committee members to determine the percentage of RAs who had received certification through the Society of Clinical Research Associates (SoCRA), the Association of Clinical Research Professionals (ACRP), or the Society of Clinical Data

Management. For this group, the rate of certification was 33%. Of those, 44% received the CCRC (certified clinical research coordinator) certification and 8% the CCRA (certified clinical research associate) certification both from ACRP, 44% the CCRP (certified clinical research professional) certification from SoCRA, and one RA (3%) reported holding both the CCRC and CCRP certifications. The salaries of certified RAs were higher than those of RAs who were not certified ($P = .0004$ by chi-squared test; Fig 4). The questionnaire also asked, "Do you feel that a SoCRA or ACRP certification should be required of RAs?" The responses were similar between "yes" (38%), "no" (35%), and "don't know" (27%).

Duties

Almost all RAs reported that they perform duties other than ACRIN data management (82%). These other duties included "other research" (49%), "administrative" (46%), "quality assurance" (17%), "patient care" (16%), "office/secretarial" (12%), "cancer registry" (5.5%), "medical records" (5.5%), "radiologic technologist" (4%), and a wide range of other duties (27%). Some RAs reported more than one additional duty.

When asked, "Which are the most challenging duties of ACRIN data management," almost half reported that "paperwork" was the most challenging duty (Table 2). Eighty-three percent of RAs indicated that their principal investigator provides the support they need to do their jobs, and 73% said they meet regularly with their principal investigator.

Resources Available for the ACRIN RA

ACRIN and the RA committee endeavored to make a number of resources easily available to the RAs, and thus provided a dedicated web page for RAs and a quarterly newsletter. We wished to find out if the RAs were aware of these resources and included several questions about this. Sixty-one percent of RAs responded affirmatively to the question "Are you aware of ACRIN RA web link located on the ACRIN home page?" Only 17% had used the link to locate a mentor or resource person. Sixty-seven percent had read the RA newsletter.

Seventy-five percent of ACRIN RAs participate regularly in ACRIN conference calls. These calls are held monthly or more often as needed to handle protocol specific issues, such as recruitment, protocol compliance, and reimbursement. The protocol principal investigator and ACRIN staff support these calls and engage the RAs in all aspects of the trial. Additionally, the Research Associate Committee hosts a day-long education session in conjunction with the annual ACRIN meeting held each fall. Fifty-five percent of respondents acknowledged that they attend the annual meeting.

ACRIN uses the internet to collect all of the study data and images, so it is important for the RA to have the hardware and computer resources available to facilitate this transfer of information. The RAs surveyed reported that 98% of them had the necessary hardware and internet connections. Ninety-five percent felt they were "very functional" or "comfortable" using the internet, whereas 12% felt they needed additional training.

DISCUSSION

To have a successful clinical research program, it is key for departmental leadership and administrators to understand the characteristics and needs of RAs. Although the principal investigator has the overall responsibility for the conduct of the trial, RAs provide the fundamental structure necessary to organize, maintain, and administer the clinical trial program.

Salary

The respondents in our survey reported that 40% earn between \$40,000 and \$59,000 per year. This result is consistent with a survey conducted in 2004 by the Society of Clinical Research Associates (4). That survey reported a median annual salary for all respondents of \$49,143. It is important to note, however, that this survey included a wide range of respondents, including those who work for industry (ie, pharmaceutical or device companies), institutional review boards, and other types of institutions not represented in our ACRIN survey. When the SoCRA survey was analyzed by subgroups, those respondents with the title of *clinical research coordinator* reported a median salary of \$39,912.

Another survey, conducted by the ACRP in 2003 (5), indicated that the median annual salary for their clinical research coordinator subgroup was \$50,000. It is unclear why the salary level of this group is higher than the SoCRA survey or than our ACRIN survey.

Education and Training

Based on the responses to the survey, it was clear to the RA committee where our focus on education and training needed to be directed. Most RAs reported that their training was primarily “on-the-job,” indicating that there is insufficient formal training at the institutional level. To better support RAs who work on ACRIN trials, the RA committee developed an online training tool to provide education on Good Clinical Practice, human subjects protection, federal regulations, and protocol specific requirements (6). Although many institutions require some human subjects protection training, the results of our survey indicate that such training was inadequate to properly conduct their jobs. Additional education should be provided in the form of orientation for new RAs, in-services, and continuing education specific to the clinical research process. This has been accomplished through the annual (day-long) ACRIN RA Fall Educational sessions, during which we provide education for both the experienced and new RAs.

Certification

Some institutions now require or encourage certification by ACRP or SoCRA as a condition for employment. The presumption is that certified RAs have undergone rigorous education in the conduct of clinical research and that training will be reinforced by continuing education required to maintain certification. That only 33% of respondents in our survey held a certification, and that only 38% felt certification should be required, puts RAs at odds with those making hiring decisions. We anticipate that more RAs will become certified as employers continue to require certification as a condition of employment.

Staffing Levels/Duties

To adequately support a clinical research program, it is important that department administration anticipate the number of RAs required to recruit and enroll a specific number of research participants. We analyzed our data in terms of patient load per full-time equivalent RA; however, a “benchmark” figure could not be determined. Imaging research studies can vary widely, from very straightforward studies utilizing new contrast agents that are completed in a few hours to complex interventional studies that require participant follow-up for many years. Staffing resources can also vary between the recruitment and follow-up phases of large population screening trials. Therefore, careful consideration of the types of studies to be conducted is needed to evaluate RA staffing levels.

CONCLUSIONS

Our survey can help administrators conducting research in the cooperative group setting to understand the needs and characteristics of RAs. We found that a common career path for

RAs is to transition from a clinical position such as a radiologic technologist to RA with little or no formal training. In today's climate of increasing regulatory oversight, institutions and cooperative groups should provide the opportunity and resources for adequate training or require RA certification through one of the professional organizations.

Acknowledgments

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Figure 1.
Types of sponsors American College of Radiology Imaging Network Research Associates work with.

Figure 2.
Salary range.

Figure 3.
Salary by supervisory status.

Figure 4.
Salary by certification status.

TABLE 1

Survey Instrument Questions

Question	
1	Are you an RA for other research groups/sponsors as well as ACRIN?
2	How long have you worked as a research associate?
3	How were you trained for your position?
4	What is your background?
5	Are you certified by SoCRA, ACRP, or CCDM? Please indicate your certification.
6	What other duties/responsibilities do you have in addition to your work as a research associate?
7	How many other RAs are there working in your department/section?
8	Do you supervise any other employees? If yes, what are the positions of the employees you supervise?
9	What was your work experience immediately prior to becoming a RA?
10	Describe your work status.
11	What is your current salary range?
12	In which state are you currently employed?
13	Type of institution in which you work:
14	What do you think is the minimum education level that should be required of RAs?
15	Do you think a SoCRA or ACRP certification should be required of RAs?
16	What do you feel are the most challenging duties of being an ACRIN RA?
17	How long did it take for you to feel comfortable with your position as an ACRIN RA?
18	Do you think that on-the-job experience is sufficient training to be a successful RA for ACRIN?
19	Are you aware of the ACRIN RA web link located on the ACRIN home page?
20	Have you accessed the RA link on the ACRIN website to locate a mentor or resource person?
21	Have you ever read the ACRIN RA newsletter?
22	How many patients on average do you enroll onto research studies per year?
23	How many patients (on average) do you follow and submit data for at least once a year?
24	How many patients, on average, does your entire department/section enroll per year?
25	Do you meet/interact regularly with the ACRIN study investigator designated at your site? If yes, how often do you meet/interact?
26	Do you feel your ACRIN study investigator offers you the support necessary to conduct your job efficiently?
27	Do you regularly participate on ACRIN conference calls?
28	Do you attend ACRIN annual meetings?
29	What kind of programs would you find helpful at annual meetings?
30	Do you have the hardware (computer/modem) with adequate Internet capability available for use at your site?
31	Please rate your skills regarding use of the Internet or web browser.
32	Do you think that you will need training in the use of the Web service in order to learn how to access ACRIN protocols?
33	What aspects of ACRIN RA training are currently working well? How can we improve our training processes and resources?

ACRIN, American College of Radiology Imaging Network; RA, ACRIN Research Associate; SoCRA, Society of Clinical Research Associates; ACRP, Association of Clinical Research Professionals; CCDM, Certified Clinical Data Manager, Society of Clinical Data Management.

TABLE 2

Responses to the Question: What do you Feel are the Most Challenging Duties of being an ACRIN RA?*

Response	Percent of Responders
Paperwork	45
Queries	33
Case report forms/data entry	33
Institutional review board	33
Time management	25
Audits	24
Financial issues	24
Subject retention	24
Working with investigator	19
Staffing	16
Patient interaction	10
Conference calls	10

ACRIN RA, American College of Radiology Imaging Network Research Associate.

* This was posed as a multiple choice question in which respondents could choose more than one answer.