Inside the Clinical Research Arena:

An Overview of Hiring Practices and Job Requirements for

Clinical Research Associates and Clinical Research Coordinators

Catherine Meldrum

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SUMMARY

The clinical research enterprise is expanding rapidly and the demand for qualified personnel is high. For most health related professions, entry level credentials include a focused didactic program, usually from an academic institution, followed by a practical, hands-on experience (internship). This has not been the case for entry level personnel in clinical research. Only recently have academic programs evolved which provide the didactic content and many include hands-on internship or preceptorship experiences. Hiring authorities focus on experience as a requirement and although they acknowledge the value of education, even with an internship or preceptorship, it often does not provide the credential necessary for hiring. The result is the double bind of needing experience to get a job but needing a job to get experience. This study was undertaken to assess the validity and extent of this situation and whether a more traditional model of education and internship as entry level criteria, is possible. Through internet job reviews and surveys from Academic Institutions, Contract Research Organizations, and Pharmaceutical Companies it was found that a combination of experience and possession of an Associate or Bachelor's degree were valuable entities to hold when entering the clinical research job market. A review of the hiring requirements for Clinical Research Coordinator (CRC) and Clinical Research Associate (CRA) positions showed that over 90% of the postings required experience, a degree, certification, or other similar experience or a combination of these traits. Clearly it is a difficult for an individual to obtain a position as either a Clinical Research Coordinator or as a Clinical Research Associate unless one has experience.

INTRODUCTION

As our understanding of science increases, the knowledge necessary to understand the process involved in the conduct of clinical research increases comparably. This is reflected in the complexity of the clinical trial, the number of patients enrolled, and the number of procedures completed during the study. In order to achieve a high level of quality in a clinical trial a well trained group of individuals is required. Research staff must be familiar with both the clinical research protocol and the regulatory requirements. Research staff are responsible for study documentation and study monitoring in order to ensure accuracy of the data in the clinical study.

The most common job titles for the support staff who conduct clinical research are the Clinical Research Associate (CRA) and the Clinical Research Coordinator (CRC). The CRA is usually a representative of the sponsor or contract research organization and their function in clinical trials is generally independent of the study site. A CRA ensures that accurate records are kept, drug accountability is ensured and all regulatory requirements are met by the study site personnel. There are many other titles which appear in job postings that may be synonymous with CRA. These include:

- Contract Clinical Research Associate
- Regional Clinical Research Associate
- Clinical Trials Associate
- Clinical Trials Professional
- Senior Clinical Research Associate

A title of Senior CRA generally indicates that the staff member has more experience in clinical trials than the entry level CRA.

A Clinical Research Coordinator (CRC) functions at the site where the clinical trial is being conducted. They maintain accurate study records and source documents, perform subject screening and patient recruitment, maintain quality case report forms, and are under the supervision of the Principal Investigator. Both the CRA and CRC perform their duties utilizing Good Clinical Practice (GCP) regulations and under the regulatory guidelines of the Food and Drug Administration (FDA).[1,2] Good Clinical Practice regulations are guidelines of the International Conference of Harmonization (ICH).[3] The ICH consists of the international union of the United States, Japan, and the European Nation. These ICH guidelines for good clinical practice are designed to protect the safety, rights and well being of human subjects in a clinical trial. They assure credible clinical data and set the international standard for conduct, reporting, recording and designing of clinical trials.[4]

Clinical research staff are not required to hold a license to practice (as are nurses or other personnel who interact with patients) but they may obtain professional credentials within their field. Traditionally the training of the CRA's and CRC's has been through on-the-job training with minimal educational preparation. Until the mid 1990's no educational programs for CRA's and CRC's existed in the academic community. New clinical research staff were often selected because they were at the right place, at the right time. Often, entry level training and continuing education for the staff group took the form of educational workshops within medical centers, national research conferences and university courses all designed to improve working knowledge of the clinical research staff. There were no formal entry level requirements for the profession.

Clinical research staff often pursue certification for various reasons, to validate knowledge and experience, for personal satisfaction, to facilitate pay increases, and for upward mobility within the profession.[5] The Society of Clinical Research Associates (SoCRA) and the Association of Clinical Research Professionals (ACRP) are two organizations which currently provide certification for clinical research staff. These certifications are viewed by clinical research staff as the current standard for the education, knowledge and experience in clinical research.[6]

The Association of Clinical Research Professionals was founded in 1976 to help educate researchers and promote ethical standards within the research field. [7] As of 2005, they have over 17,000 members. Despite the fact that certification is not a requirement to enter the job or remain in the field there have been over 13,000 research professionals certified by the ACRP since the first exam was offered in 1992.[8] The certification examination for ACRP involves three separate examinations. [9] The three examinations are designed for each of the following research staff; Research Associate, Research Monitor, and Research Investigator. Two years of clinical research experience is required prior to taking the examination. After successfully passing the role-designated exam the individual may use the titles CCRA (Certified Clinical Research Associate), CCRC (Certified Clinical Research Coordinator), or CCTI (Certified Clinical Trials Investigator).

The Society of Clinical Research Associates was founded in 1991. [10] SoCRA provides one examination for staff with a research background. This may include physicians, nurses, and individuals with a background in business administration, medical

technology and other areas. [11] The individual must be a member of SoCRA and meet one of the following eligibility requirements:

- Worked full-time two years in the research field
- Worked part-time five years in the research field
- Have a minimum of an Associate Degree in "Clinical Research" and 1750 hours employment in the clinical research over two years
- Have a minimum of an Associate Degree in a science or health related science, completion of 12 credit (semester) hours at a college or university in the area of clinical research and 1750 hours employment in clinical research over two years [12]

Upon successful completion of the examination the designated initials CCRP (Certified Clinical Research Professional) may be used. [13]

To be eligible to take either the SoCRA or ACRP exam there is a requirement to have actual working experience within the field. Recertification with either organization requires a fee as well as validated continuing education credits. Each organization has a requirement of the number of research related continuing education credits staff must accrue to be recertified by that organization.

Given the continuing demand for increasing numbers of capable staff to support the clinical research enterprise, it is both frustrating to entry level candidates and surprising to the educational community that experience and not education is the most important hiring criterion. In addition, it is even more surprising that experience is never defined or qualitatively evaluated in the hiring process.

The hiring practices of, industry, and CRO's, and to some degree clinical sites need to be evaluated, the entry level criteria for the profession need to be established and the credentialing process needs to be revised to meet a national standard. This study was undertaken to determine actual hiring practices of hiring authorities within the area of clinical research and seek out and define the rationale behind these practices.

METHODS

A review of job postings specific for clinical research associates and clinical research coordinators was completed during the months of August, September, and October 2004. This review was accomplished by searching the internet using various search engines and typing in key words for clinical research jobs. A survey (appendix A) was developed to gather further information on the hiring practices of organizations. The survey was mailed to organizations that employ clinical research staff. Organizations were chosen by two methods. First the internet was searched for Pharmaceutical companies. Over 220 companies were found but only those based in the United States were contacted. Other organizations, mainly academic health centers conducting clinical research solicited were via by email contact through the Clinical Research Administration Program at Eastern Michigan University. Table 1 is a list of the organizations that were mailed the survey.

Table 1

Organizations Contacted for Survey Information

3M	Mayo Clinic, Rochester
Abbott Laboratories	Mead Johnson
Alpha Rx	MGH Clinical Research Program, Massachusetts General Hospital
Amgen	Northwestern Center for Clinical Research
Barr Facilities	Novartis Pharmaceuticals
Bayer	NPS Pharmaceuticals
Berlex	NV Organon
Blanshett	Office of Clinical Trials, UCLA
Boehringer-Ingelheim	Paddock Laboratories
Bristol-Myers	Pfizer Inc.
Center for Pediatric Research, Eastern Virginia	Pharmion Corporation

Medical School	
Center for the Advancement of Clinical Research, University of Michigan	Purdue Pharma L.P.
ChemDiv	Reliable Biopharmaceutical Corporation
Cleveland Clinic	RIA International
Clinical Trials Office, James Brown Cancer Center	Samaritan Pharmaceuticals
Clinical Trials Program, Indiana University	Sandoz
CPL, Inc.	Sepracor
Duke University	SP Pharmaceuticals
Eli Lilly	STADA Pharmaceuticals
Endo Pharmaceuticals	StatProbe
Fougers	SUNY Upstate Medical University, Clinical Trials Office
Fujisawa	Synthetic Blood International
Genetech	Taro Pharmaceutical Industries
Gilead	Texas Tech University Health Sciences Center, Division of Clinical Research
Global Pharmaceuticals	University of North Carolina, Office of Clinical Trials
Granard	University of Wisconsin
GlaxoSmithKline	Upsher-Smith Laboratories
Hawthorne Pharmaceuticals	VersaPharm Incorporated
Himalaya	Vyteris
Hoffman/Roche Diagnostics	Watson Pharmaceuticals
Impax Laboratories	Wyeth
Johnson & Johnson	Yale Pharmaceutical
Kansas University Medical Center Research Institute	

A total of 65 surveys were sent via postal mail and electronic mail. Initial contact was made by email if an email address was available. There were 53 organizations that had an email address. Surveys were sent to these 53 organizations. If a response was not received by email, contact was made by postal mail. This was done by a letter along with the survey and a stamped self-addressed envelope for convenience of return. The twelve centers without available email addresses were initially contacted by postal mail

utilizing the above same approach. A second letter was sent if no response was received within 8 weeks.

RESULTS

During the 3 month internet search of job availability there were 206 job postings found for clinical research staff personnel. Job descriptions for Clinical Research Associates and Clinical Research Coordinators were reviewed separately for experience and education requirements needed for hiring. Project Manager positions were not reviewed. Clinical research experience requirements for job postings were categorized into the following:

- No research experience needed
- 1-2 year's of research experience needed
- 3-4 year's of research experience needed
- 5 or more year's of research experience needed
- Other experience required
- Degree required
- Certification required or preferred

The first review to determine experience hiring requirements for hiring was completed on Clinical Research Coordinators. Figure 1 shows the degree of experience as it relates to hiring requirements for Clinical Research Coordinators. For the purposes of obtaining data on this group any job posting that indicated the classifications of; clinical research coordinator, clinical trial coordinator, and clinical coordinator were incorporated into this chart. Only 8% of the job postings at the time of this review stated "no experience necessary". 34% of the job postings required some type of "other"

experience. The following is a list of experience specifications for "other experience" required for the CRC position:

- Experienced CRC
- Experience in patient recruiting and screening
- Demonstrated knowledge of clinical trials
- Phase 1 experience required
- Industry experience required
- Experience in medical therapeutic area
- Recent clinical research experience necessary
- BS/BA and clinical research experience or equivalent
- Scientific experience minimum
- Practical research experience required

30% of the CRC job market postings required the candidate to have an associate or bachelor's degree while 11% required or preferred the candidate to have certification by either the SoCRA or ACRP organizations.

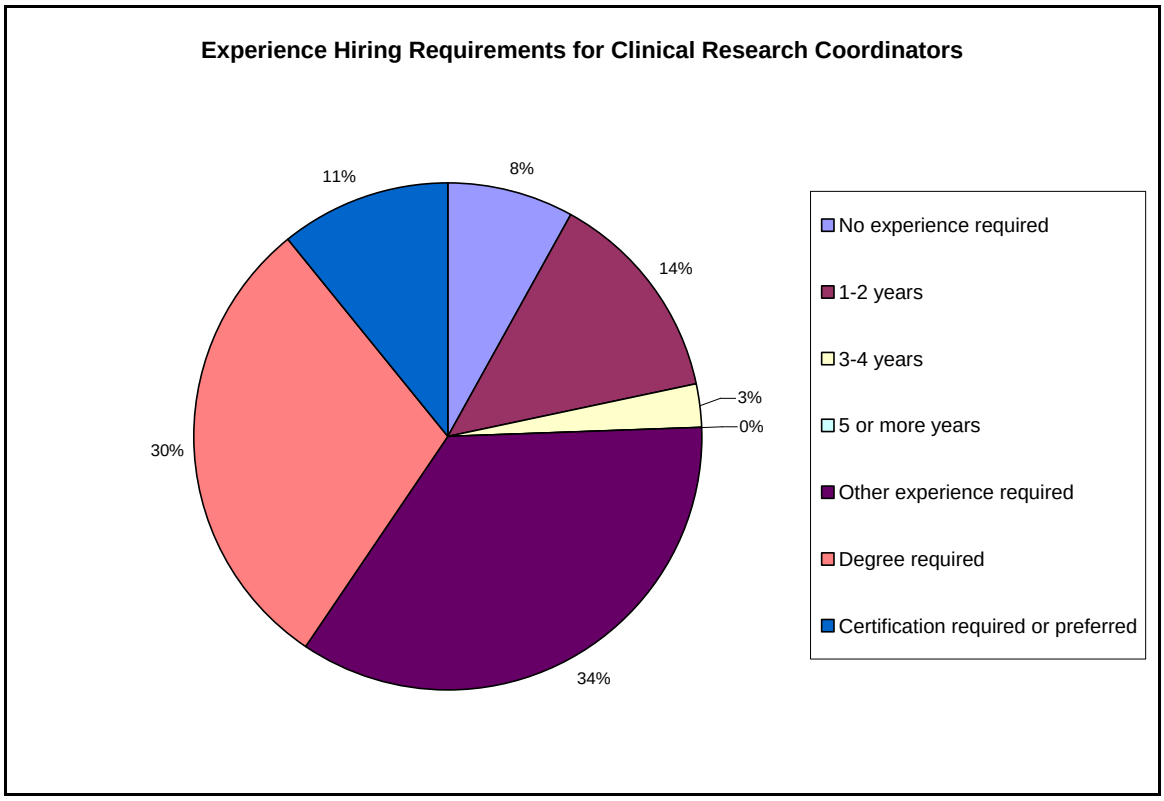

Figure 1

A separate review of experience hiring requirements was completed for Clinical Research Associates. Figure 2 shows experience requirements for associate, senior, contract, regional, in-house, monitor, clinical trials professional and clinical trials associate. While Senior CRA's do require more experience it was found that of the 184 CRA postings reviewed 31 postings were designated as a Senior CRA positions. 16% of the postings were designated as CRA/Senior CRA. 1% of all job market postings had "no experience" listed or no information on experience requirements for the desired position. 33% of the postings required staff to have at least 1-2 years of clinical research experience while 13% of the listings required 3-5 years experience. It is of interest to note

that only 3% of the posting during the time of the review desired or required professional certification of staff.

Under the section “other experience or no numerical amount specified” a wide variety of requirements were seen. This category represented 11 % of the job postings reviewed. Some postings required experience, education, certification or a combination of these. An academic degree was also required for 39% of the CRA job postings. The degrees mentioned included the BS in Health or Life Science, BA, RN, BSN, CNS, biomedical, pharmacy, a combination of the above degrees or “equivalent”. The most common degree was the nursing degree which was required in 48% of the postings requiring education. 34% of the postings required “other experience”. The following is a list of “other experience” required for the CRA job postings:

- Demonstrated knowledge of clinical trials
- Phase 1 experience required
- Industry experience required
- Experience in medical therapeutic area
- Recent clinical research experience necessary

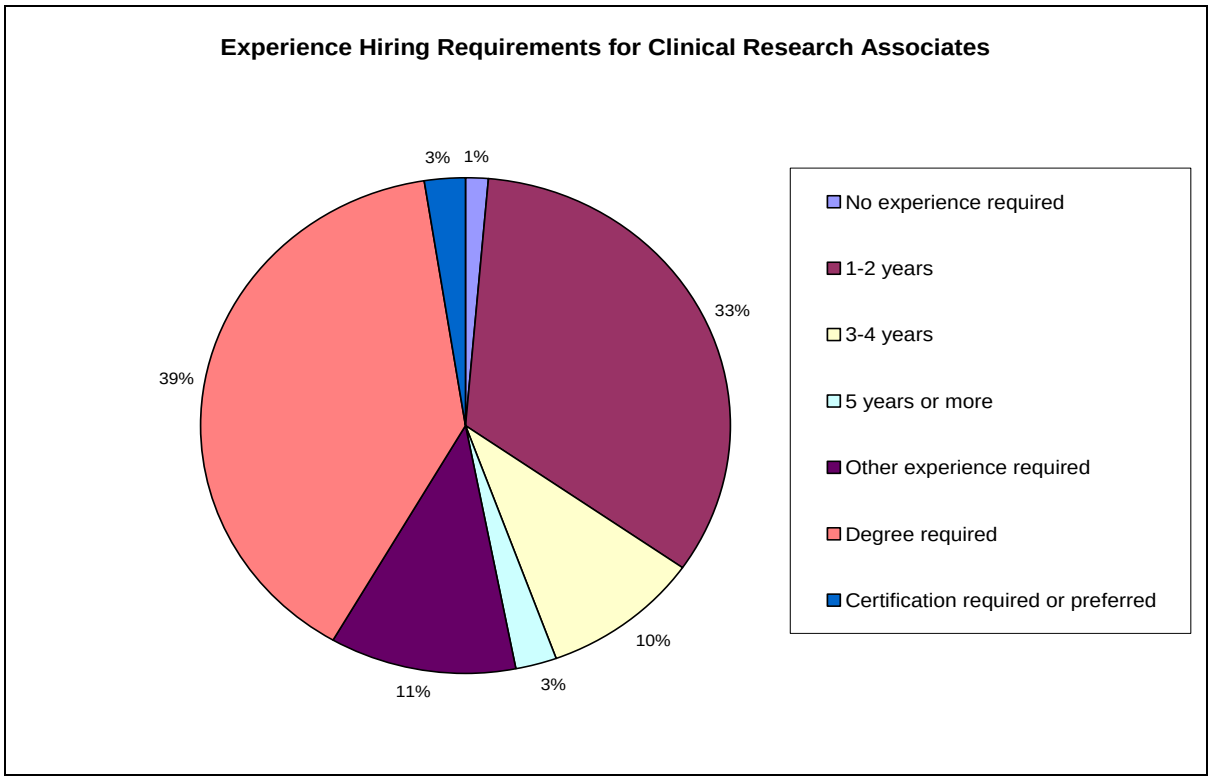

Figure 2

Following the review of job postings for both CRA and CRC positions it is noted that many companies continued to seek individuals experienced in clinical research for their available positions despite the demand for research personnel.

Tables' 2-6 present data on hiring practices of clinical research staff obtained from the survey. The survey was sent to 65 organizations. 14% of the participants responded in writing that they declined to participate. The response rate for the survey was 24%.

The top three responses to how a company seeks new employees were:

1. Post job availability on company website
2. Networking
3. Internet job postings

Quite surprisingly it was found that no one stated they would utilize Recruiting Agencies, Internet Resumes, or Independent Contractors as a method to hire more staff.

The amount of time in obtaining a new hire varied between 1-6 months. Table 2 shows the overall percentage rates in hiring this new staff.

Table 2

Average Time in Hiring New Personnel

2 weeks or less	0
1 month	42%
Up to 3 months	42%
3-6 months	16%
Over 6 months	0

Table 3 shows the estimated cost of hiring new personnel. The cost of adding additional staff is of concern to any employer. According to the Institute of Aging Services (IFAS) it is estimated that in the United States the average cost of hiring new long-term care staff is $3,500.[14] The annual price tag with staff turnover in this industry alone is almost $4.1 billion.[15] In order to assess how this would financially impact employers hiring research staff organizations were asked to give an estimate of the costs commonly incurred in hiring a new individual. 92% stated the costs would be held to $1500.00 or less. 84% responded that it would take an employer 1-3 months to hire a new employee, still the cost associated with that time interval was $1500.00 or less.

Table 3

Estimated Cost of Hiring New Personnel

$500.00 or less	50%
$1500.00	42%
$2500.00	0
$3500.00	0
Over $5000.00	8%

Organizations were asked if the value of academic credentials in clinical research enhanced the desirability of the candidate to the employer. 92% responded that it did enhance the desirability of the potential candidate.

Almost every new hire within the clinical research enterprise undergoes some type of orientation process. Table 4 shows the components of the orientation process required by the organizations who responded to the survey. Each organization was given the following list and asked to check which components on the list were included in their orientation process. Every organization checked all items.

Table 4

Components of Orientation Process Required in Each Organization

General company regulations and procedures	100%
Tour of facility	100%
Performance expectations	100%
Understanding of human resource benefits	100%
Internship working with another staff member in the same job classification	100%

There are many components to the orientation process which are specific to the organization. Organizations were allowed to "write in" additional orientation requirements that were not on the above list. These additional requirements included:

- The employee read applicable regulations.
- The employee attend a "specific 5-day training course"
- The employee must attend monthly research education programs.
- The employee must take part in discussions related to the Federal Regulations, IRB regulations, Site specific logistics and procedures, and Standard Operating Procedures (SOP'S)

A key element in one organization was a more individualized approach to the orientation process. The organization had a policy that if the research coordinator had less than 2 years of clinical research experience within their facility a mandated 3-day training program was required. In another organization, a week- long training occurred in which Standard Operating Procedures (SOP), monitoring procedures, workflow procedures, project management concepts, and unit interrelations were discussed. The new hire then worked with other staff members who subsequently completed a proficiency check off sheet for the new employee.

The survey showed that the time required to actually identify and hire a new employee is between 1-6 months. As is the case in most professions the entry level employee is minimally productive. Orientation processes vary from company to company largely depending on the experience of the individual, the requirements of the job, the availability of staff to assist in the orientation process, and a host of other factors. The survey requested that the employer estimate what the applicable time frame was for

the new hire to complete orientation within their organization. Table 5 shows the choices and response percentages for personnel orientation time frames.

Table 5

Estimated Time Frame to Complete Orientation for New Personnel

1 week	17%
2-4 weeks	33%
5-7 weeks	25%
Over 8 weeks	25%

Organizations were also asked if they would consider hiring staff educated in clinical research with minimal experience rather than relying on experienced staff only. 75% of the organizations responded "yes". 25% responded "no.

The internet survey of CRA and CRC jobs postings indicated many companies required experience prior to hiring. The survey requested employers state how much clinical research experience their staff had at the time of hiring. Table 6 shows the number of years a CRA's and CRC's had at the time of their hiring within the organization.

Table 6

Years of Experience CRA/CRC Had at Time of Hire at Surveyed Organization

Years of Experience	CRA	CRC
0-1	40%	52%
2-5	56%	39%
6-10	4%	7%
11 or more	0%	2%

60% of the CRA's hired had 2-10 years experience at the time of hire. 46% pf CRC's had 2-10 years experience at the time of hire. 2% of the organizations hired staff with 11 years or more experience but this was applicable to the CRC role only.

Additional comments or characteristics were requested on hiring, training procedures, or education specific to the organization when hiring a new employee. The following comments were received:

- The amount of enthusiasm and personality that staff can bring to a project in an effort to motivate all involved in the project.
- Personality and enthusiasm were felt to be more of a concern for their organization over the education or experience an individual held.
- One organization collaborated with their Human Resources Department to review and revise all clinical research job descriptions. Following their review new clinical job levels in clinical research were implemented, one of which included a new entry-level position which required no experience. This was a new concept for the organization so no data on success of the project is available at this time.

CONCLUSIONS

Despite the increasing need for clinical research staff in CRA and CRC roles the hiring expectation is that they have experience. There is no provision for entry level skills, but without experience the method to enter the field remains unclear. The question is, "Is having experience that critical or could a company utilize staff trained in clinical research and provide them with an orientation within their organization?" In other allied health disciplines (nursing, medical technology, dietetics, etc.) individuals complete a program of coursework at an accredited educational institution, complete a hands-on internship, are hired and provided an orientation by their employer. What makes the clinical research field different in this aspect?

Educated clinical research staff who did gain employment still go through the same orientation process as those without an education. In the survey of employers, comments were requested if the employers answered "yes" to altering the orientation process for hires with an educational program in their background. No comments were requested if the pre-scheduled orientation process did not change. This was a weakness in the survey design. If the survey had solicited an explanation for why the orientation process was not changed for educated staff it may have provided further insight into the hiring practice rationale in clinical research. If an organization hires an educated clinical research individual why could they not tailor the orientation and possibly decrease the amount of time for the orientation process thereby gaining a productive employee more quickly?

Another question asked in the survey was the amount of experience staff held at the time of hiring within the organization. While it was noted that 46% of CRC's and 60% of CRA's had more than 2 years experience at the time of hiring the survey showed that a higher percentage may have had much more extensive experience at the time of hire. The survey included a category of 0-1 year's experience. The survey results reported that 92% of CRC's and CRA's were in this category. The survey did not have a category of hiring with no experience. Due to the survey design it is not possible to distinguish how many of those 92% had no experience or 1 year experience at the time of hire.

The survey provided a basic overview of the hiring requirements for clinical research personnel. The survey indicated that it could take up to 6 months at a cost of up to $1500 for an employee to be productive within the organization. This time includes the orientation process one must undergo. Quite interestingly, if the potential employee had academic credentials in the area of clinical research it enhanced the desirability of the candidate to the employer, but it did not change the time of the orientation process for the newly hired personnel. The survey showed that 67% of employers stated that the orientation process was not altered due to the employee having academic credentials in clinical research. Of those who responded "yes the orientation process was altered" only one organization allowed for areas of orientation to be eliminated that the employee was already familiar with. The survey did not ask how this was determined (e.g. by a written exam, or review checklist or verbal communication with the staff member). In addition another organization that responded "yes to altering the orientation process" and

specified that orientation may be shortened due to the knowledge the candidate already possesses but all components of the orientation were still reviewed on an individual basis.

There are many courses and training programs available to clinical research staff. Programs are available at universities for academic credit, but do not yet lead to clinical research certification by a professional organization. Masters Degree programs are available and are valuable in facilitating upward mobility in the profession for those already employed in the clinical research field. There are also many clinical research training conferences held by academic health centers. The ACRP holds classroom courses on a variety of topics such as Budgeting, FDA Audits, and Accompanied Site Visits as well as over 36 online research courses for educational credit.[16] Do these really assist the candidate in obtaining employment? According to the survey results, yes!

Recently clinical trials have been closely scrutinized by the national media, by the FDA and quite commonly the clinical research enterprise has been held in a negative light. Multiple pharmaceutical products have been removed from the market. Was this due to errors or oversights in the clinical research process leading up to their approval? Is it possible that better educated staff personnel (coordinators, monitors, project managers, etc.) might have done a better job in the clinical research arena. The ultimate goal of hiring educated staff is increasing the standards in performance of clinical trials. Realizing the importance of education is a requirement for every organization employing clinical research staff. Utilizing competent educated staff results in accurate data collection within trials and the potential for a broader understanding of the regulatory requirements of clinical research. In 2002, the average CRC in an academic center was responsible for four active trials.[17] Given the time constraints and regulatory

responsibilities, this is a job filled with professional pressures, a required depth of knowledge, as well as achieving efficient and effective performance. Attracting educated staff and retaining them in the end will improve the success and efficiency of the clinical trial study.

Why then do the hiring criteria of those surveyed still rely on experience as the major determinant of the acceptability for new personnel? Why do organizations spend up to one fourth of a year bringing new staff "up to speed" without major changes in the orientation process for educated or experienced staff requiring less orientation time? Organizations need to re-evaluate their hiring processes. While the response to this survey was smaller than anticipated, the responses showed an amazing degree of similarity for each job classification and can probably be viewed as the norm for the industry.

In conclusion, as the educational opportunities in clinical research continue to increase and the number of individuals entering the job market with these credentials continues to increase, organizations should implement new hiring criteria which recognize these educated individuals and the increased quality that they bring to the organization.

Appendix A

Clinical Research Staff Hiring Questionnaire

Need for increased staff: As you become aware of the need to hire staff what are the specific steps you take to implement the process of hiring?

Please check all that apply:

□ Trade Publications
□ Recruitment Agencies
□ Networking
□ Conferences
□ Internet Resumes Services
□ Internet Job Listings
□ Previous Employees
□ Post job availability on company website
□ Use of independent contractors
□ Other (please explain):_____

Time/Cost Issues: What is the average time and cost in obtaining a new hire?

Please check applicable time frame:

□ 2 weeks or less
□ 1 month
□ Up to 3 months
□ 3-6 months
□ Over 6 months

Please check estimated cost incurred:

□ $500.00 or less
□ $1500.00
□ $2500.00
□ $3500.00
□ Over $5000.00

Does the possession of academic credentials in the area of clinical research enhance the desirability of this candidate?

□ Yes
□ No

How does the possession of potential employee having academic credentials compare to previous experience?

□ Does not alter the hiring process
□ Would hire credentialed individual over experienced individual
□ Would hire experienced individual over credentialed individual
□ Institution requires both degree and experience

Additional comments: _____

Orientation of new hire: Can you please elaborate on which components listed below are included in your New Personnel Orientation Program.

Please check all that apply:

□ General company regulations and procedures
□ Tour of facility
□ Performance expectations
□ Understanding of human resource benefits (ex. insurance, vacation, sick time)
□ Preceptorship with another staff member in the same job classification
□ Other (please explain):_____

Estimated time frame to complete New Personnel Orientation:

Please check most applicable time frame:

□ 1 week
□ 2-4 weeks
□ 5-7 weeks
□ Over 8 weeks

Does the possession of academic credentials in the area of clinical research change the orientation process?

□ No
□ Yes (if checked please explain):_____

Would your company hire formally educated staff with a degree in clinical research, but with minimal experience and provide them with an orientation, rather than relying on obtaining experienced staff only?

□ Yes
□ No (if checked please explain):_____

For entry level CRA and CRC positions within your organization, can you provide estimates as to the amount of experience they have at the time of hiring?

Using the following percentages as guidelines please choose a percentage for each group listed below:

0% 25% 50% 75% 100%

CRA	%	CRC	%
0-1 yr experience	____	0-1 yr experience	____
2-5 yrs	____	2-5 yrs	____
6-10 yrs	____	6-10 yrs	____
>11 yrs	____	>11 yrs	____
Do not hire CRA's	____	Do not hire CRC's	____

Is there any other information that you would like to provide regarding hiring, training procedures, or education specific to your company when bringing in a new employee?

_____
_____

Company Name: _____
Location of company: _____
Type of organization (ex: CRO, Pharmaceutical, Academia):_____

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