

Clinical Researcher

June 2020

HOME STUDY TEST

THE MORE THINGS CHANGE...

Earn 2.0 Continuing Education Credits

Two articles from the June 2020 issue of *Clinical Researcher* have been selected as the basis for a Home Study test that contains 20 questions. For your convenience, the selected articles and test questions are combined and posted in the form of this printable PDF at

<https://www.acrpnet.org/professional-development/training/home-study/>, where the

test may be purchased. *The test will be active until June 30, 2021.* This activity is anticipated to

take two hours. **Answers must be submitted using the electronic answer form online**

(members \$30; non-members \$50). Those who answer 80% or more of the questions

correctly will receive an electronic statement of credit by e-mail within 24 hours. Those who do

not pass can retake the test for no additional fee.

The *Clinical Researcher* archive is at <https://www.acrpnet.org/resources/clinical-researcher/>.

CONTINUING EDUCATION INFORMATION

The Association of Clinical Research Professionals (ACRP) is an approved provider of clinical research continuing education credits.

Contact Hours

The Association of Clinical Research Professionals (ACRP) provides 2.0 contact hours for the completion of this educational activity. These contact hours can be used to meet the maintenance requirements for certification programs of the Academy of Clinical Research Professionals. (ACRP-2020-HMS-006)

ACRP DISCLOSURE STATEMENT

The Association of Clinical Research Professionals (ACRP) requires everyone who is in a position to control the planning of content of an education activity to disclose all relevant financial relationships with any commercial interest. Financial relationships in any amount, occurring within the past 12 months of the activity, including financial relationships of a spouse or life partner, that could create a conflict of interest are requested for disclosure. The intent of this policy is not to prevent individuals with relevant financial relationships from participating; it is intended that such relationships be identified openly so that the audience may form their own judgments about the presentation and the presence of commercial bias with full disclosure of the facts. It remains for the audience to determine whether an individual's outside interests may reflect a possible bias in either the exposition or the conclusions presented.

ACRP EDITORIAL ADVISORS

Suheila Abdul-Karrim, CCRA, CCRT, FACRP
Victor Chen, MSc
Stefanie La Manna, PhD, MPH, ARNP, FNP-C
Christina Nance, PhD, CPI
Paula Smailes, DNP, RN, MSN, CCRP, CCRC
Jerry Stein, PhD, ACRP-CP
Shirley Trainor-Thomas, MHA
Heather Wright, CCRC:
Nothing to Disclose

ACRP STAFF/VOLUNTEERS

James Michael Causey (*Editor-in-Chief*)
Gary W. Cramer (*Managing Editor*)
Jan Kiszko, MD
Deepti Patki, MS, CCRC
Barbara van der Schalie
Nothing to Disclose

PEER REVIEWED

Impact of a Risk-Based, Study-Specific Training Program on Research Coordinator Competency

Jessica Fritter, MACPR; Melissa Metheny, BSN, CCRC; Sally Jo Zuspan, RN, MSN



Clinical research coordinators (CRCs) are on the front lines of clinical research and play an integral role in human subjects' protection and protocol adherence. Despite this critical role, many CRCs report inadequate training for the roles to which they were assigned.{1}

The Pediatric Emergency Care Applied Research Network (PECARN) is the only federally funded pediatric emergency research network in the United States. The network was established by the Health

Resources & Services Administration, Maternal Child Health Bureau, Emergency Medical Services for Children program in 2001. It is currently comprised of 18 clinical centers (Hospital Emergency Department Affiliates) and nine Emergency Medical Services Agencies.{2}

There are approximately 80 CRCs across PECARN sites that contribute to PECARN research studies. Our recent work concluded that many PECARN CRCs feel less than competent to perform their jobs adequately after their institutional onboarding process.{3} Despite local institutional onboarding programs that include shadowing, web training, simulation, and online courses, most CRCs did not report feeling confident to conduct clinical research.

From this prior work, we suggested that there is a need for CRC core competency training and education in clinical research. Recent regulatory changes in Good Clinical Practice (GCP) Guidance (ICH E6(R2) from the International Council for Harmonization) recommend that a risk

assessment process should be used to identify key study activities that pose a risk to patient safety, data integrity, or regulatory compliance.^{4} High- and moderate-risk study activities should have a risk mitigation plan and a method for evaluation of these risks throughout the trial. We studied whether a targeted, competency-based training program focused on moderate to high risks would result in high levels of competency and performance in CRCs.

We conducted our study while PECARN implemented the Traumatic Injury Clinical Trial Evaluating Tranexamic Acid (TXA) in Children (TIC-TOC) study.^{5} The TIC-TOC study is a multicenter, randomized, double-blinded, placebo-controlled trial collecting preliminary data on the safety of TXA in severely injured children and the feasibility of conducting a large definitive trial.

Our study-specific, competency-based training program combined both the Joint Task Force Competency Domains (JTFCDs) and the ICH E6(R2) risk assessment process into a training program for PECARN CRCs.^{1,4} We evaluated perceived competency of CRCs in the PECARN based on the JTFCDs.

Our objective was to determine whether a targeted, competency-based training program focused on moderate- to high-risk aspects of a specific trial would result in both perception of competency among CRCs and actual performance competency on required study activities. We hypothesized that a CRC competency-based training program targeting high- and moderate-risk protocol activities would result in CRCs reporting that they felt competent to perform study activities as well as demonstrate their competency in performance of key study tasks.

Methods

We designed a risk-based, study-specific competency training program, including a study training plan and simulation activity. The study team at the PECARN Data Coordinating Center (DCC) and the TIC-TOC study lead investigators completed a risk assessment of the trial protocol, based on the ICH E6(R2) guidelines, prior to study implementation.

The study team identified risks to subject safety and data integrity. Once these were defined, they then evaluated the risks for probability of occurrence, impact to the study data or subject safety,

and likelihood of detection at the DCC. We identified several high-to-moderate risks in this trial. This includes administration of study drug in a chaotic Emergency Department environment, limited time windows to complete study procedures, three study arms with mg/kg dosing, enrollment of children with or without parents present, and time-sensitive eligibility criteria.

We then developed a training plan (see [Appendix A](#)) that included a staff training checklist incorporating competency domains and the key study risks. Due to the complex nature of the TIC-TOC study procedures, we also devised a simulation activity in which CRCs could demonstrate competency of study skills inside their own Emergency Department.

A simulation activity is a common training exercise in medical settings where a patient scenario is created and participants must manage decision-making and treatment and assessment activities. Teams may use either a verbal outline of interventions (often known as a table top activity) or fully enacted role-play using patient mannequins and real medical interventions. The choice of table top or fully enacted simulation activity was selected by each site based on its standard approach to training simulations.

Simulations or mock trauma scenarios are a common training method in Emergency Departments, and all sites practiced trauma simulations routinely. Simulations can be a useful tool in training staff in research.^{6} It took approximately four hours for CRCs to complete the study checklist and between 45 and 90 minutes to complete the simulation.

We also developed two surveys to evaluate the self-perceived competence of CRCs after site initiation training (competency survey) and after a study-specific simulation scenario. We piloted the competency survey among independent clinical research staff, including project managers and data analyst, for face validity. Under 45 CFR 46.101 of the *Code of Federal Regulations*, the Nationwide Children's Hospital Institutional Review Board found the study to be exempt from the need for further review.

The in-person CRC training session for the TIC-TOC trial covered the study protocol, enrollment activities, and basic research competencies such as regulatory, ethics, and human subject safety. We also included mock scenarios during the in-person training session that highlighted moderate- and high-risk key procedures that could pose a risk to subject safety or data integrity

based on the risk assessment. The mock scenarios allowed CRCs to practice key procedures in a low-stress training environment as a preparation for the simulations that would be held at their respective sites.

High- or moderate-risk trial procedures are ones that are judged to be complex, vary from standard of care, or must be administered within a strict timeline to avoid protocol deviation. For example, the TIC-TOC study protocol required drug administration within the specific time window from the time of injury. A miscalculation in this time window might not allow enough time for randomization and drug administration.

The study population was 20 emergency medicine CRCs from four hospitals in PECARN participating in the TIC-TOC trial. Respondents were recruited by e-mail and completed the competency survey using a REDCap survey tool after completing the study training. Once the survey tool was completed, CRCs were required to complete the study-specific simulation activity (described below) in their respective Emergency Departments.

After the simulation activity, participants completed a post-simulation survey to evaluate their perceived competence after the simulation exercise. The trainings, surveys, and simulations were administered prior to site enrollment, in April 2018. We did not use a “pre-post” survey design in this study for timing and logistical reasons. We designed this study to demonstrate perceived and actual competency, but were unable to evaluate these specific items prior to the training implementation.

Description of Survey Tools

We administered the competency survey to the CRCs at the completion of the study training. The survey collected demographic information and perceived competence in areas relevant to the TIC-TOC trial. CRCs scored their perceived competence on a Likert scale from “not at all competent” to “very competent.” The competency survey delineated study procedures into each competency domain (see Table 1) in both a competency and survey pathway. Results were analyzed to measure CRCs’ level of perceived competence after completing the risk-based, study-specific competency training session.

Table 1: Competency and Survey Pathway

Scientific Concepts and Research Design	<ul style="list-style-type: none">• Explaining Phase II trial• Identifying key data required for outcome measures
Ethical and Participant Safety Considerations	<ul style="list-style-type: none">• Informed consent• Human subject protections
Investigational Products Development and Regulation	<ul style="list-style-type: none">• Study drug dosage• Identifying adverse events/serious adverse events (AEs/SAEs)
Clinical Study Operations (GCPs)	<ul style="list-style-type: none">• Inclusion/exclusion criteria• Collection procedures• Randomization process• ICH E6(R2) GCP guidelines
Study and Site Management	<ul style="list-style-type: none">• Site-specific workflow
Data Management and Informatics	<ul style="list-style-type: none">• Electronic data capture systems
Leadership and Professionalism	<ul style="list-style-type: none">• Leadership and professionalism
Communications and Teamwork	<ul style="list-style-type: none">• Communicating key information to site personnel (i.e., physicians, nurses, pharmacists, etc.)

Description of Simulations

After we surveyed the CRCs, each site held study-specific simulations conducted in the Emergency Department trauma resuscitation area or a table top simulation with trauma team members. A clinical research moderator led the simulation at each Emergency Department using a script and a list of specific tasks and procedures identified by the risk assessment and the JTFCD competencies (see [Appendix B](#)).

Participants were presented with patient-specific scenarios that might occur during an enrollment. Participants were evaluated on a pass/fail basis based on their performance of key study activities using a standardized tool that assessed competence in study-specific skills.

Each participant was required to successfully complete the simulation activity with a passing score. Passing was defined as completing all five sections of the simulation activity accurately according to the protocol. Participants were allowed three attempts to successfully pass the simulation activity. The study activities included screening and eligibility, informed consent,

study drug administration/randomization, baseline activities/sample collection, and follow-up and AE/SAE reporting.

The data analyzed included the results from two surveys evaluating perceived competence among participating CRCs in the TIC-TOC study after completion of the staff training checklist and the simulation, and the CRCs' results (pass/fail) from the study-specific simulation.

Results

There were 20 survey participants with varying backgrounds (see Table 2).

Table 2: Competency Survey Demographics

	n (%)
Job Title	
Enroller	0 (0%)
Research Assistant	5 (25%)
Research Coordinator	13 (65%)
Research Associate	0 (0%)
Research Manager	2 (10%)
Other	0 (0%)
Years of Experience in Clinical Research	
<1 year	5 (25%)
1 to <2 years	5 (25%)
2 to <3 years	4 (20%)
3 years or more	6 (30%)
Clinical Research Certifications Obtained	
Certified Clinical Research Associate (CCRA)	3 (15%)
Certified Clinical Research Professional (CCRP)	1 (5%)
Certified Clinical Research Coordinator (CCRC)	3 (15%)
Other	13 (65%)
Highest Level of Education	
High School Diploma or GED	0 (0%)
Associate Degree	0 (0%)
Bachelor's Degree	16 (80%)
Master's Degree	4 (20%)
Doctoral Degree	0 (0%)

After the training, more than 80% of CRCs reported feeling “very competent” in informed consent, GCP, and leadership and professionalism. Most CRCs reported being “very competent” in the definition of the trial, the study outcome, study drug dosing, inclusion/exclusion criteria, workflow, electronic data capture, and communication. About half of the CRCs reported being “very competent” in sample processing, randomization, and defining the study outcome. The remainder indicated they felt “somewhat competent” in these areas (see Table 3). Few CRCs indicated they felt “slightly competent” or “not at all competent” in these areas. CRCs reported varying levels of competence in understanding and reporting safety and AE/SAE issues in the trial, with 50% feeling “very competent,” 30% feeling “somewhat competent,” and 20% “slightly confident.”

Table 3: Competency Survey Results

Scale: 1=Not at all competent; 2=Slightly competent; 3=Somewhat competent; 4=Very competent

Scientific Concepts and Research Design	3.5 (0.46)
After reading the protocol, how competent do you feel in explaining the definition of a Phase II randomized, double-blinded, placebo-controlled trial?	3.65 (0.49)
After reading the protocol, how competent do you feel in identifying the key data elements required for the primary outcome measure of the trial: the total amount of blood products transfused in the initial 48 hours?	3.35 (0.59)
Ethical and Participant Safety Considerations	3.83 (0.28)
Regarding the site-specific informed consent document, how competent do you feel in describing all eight required elements of informed consent to prospective participants in the trial?	3.75 (0.55)
Regarding your site’s specific informed consent document, how competent do you feel in selecting an appropriate location where you will discuss informed consent with the family?	3.75 (0.55)
Regarding Protection of Human Subjects, how competent do you feel in understanding protection of human subject's guidelines from required training? (This may include CITI training or other site-specific systems.)	4 (0)
Investigational Products Development and Regulation	3.45 (0.67)
How competent do you feel in determining the appropriate dose of study drug to give to the participant?	3.6 (0.68)
How competent do you feel in understanding how to identify and report AE/SAEs and other participant safety issues?	3.3 (0.8)
Clinical Study Operations (GCPs)	3.61 (0.43)
How competent do you feel in applying the inclusion and exclusion criteria to evaluate subject eligibility?	3.7 (0.47)
How competent do you feel about collection procedures including sample processing, sample storage, tube priority, storage, and shipping of study samples?	3.55 (0.6)
How competent do you feel in understanding the randomization process and what to do if the Use Next Box is not available?	3.35 (0.93)

Regarding Good Clinical Practice (GCP), how competent do you feel in understanding the ICH E6(R2) GCP guidelines around conducting clinical trials?	3.85 (0.37)
Study and Site Management	3.65 (0.59)
How competent do you feel with your site-specific work flow and carrying it out to complete enrollment of participants in compliance with the protocol?	3.65 (0.59)
Data Management and Informatics	3.68 (0.54)
Regarding electronic data capture (EDC) systems, how competent do you feel in utilizing OpenClinica and REDCap?	3.75 (0.44)
In regards to EDC, how competent do you feel in utilizing Query Manager?	3.6 (0.82)
Leadership and Professionalism	3.95 (0.22)
How competent do you feel in your leadership and professionalism skills?	3.95 (0.22)
Communications and Teamwork	3.75 (0.44)
In regards to Communication, how competent do you feel in communicating key information to all site personnel involved in the study (i.e., Emergency Department clinicians, nurses, pharmacists)?	3.75 (0.44)

Fourteen out of the 20 CRCs successfully completed the simulation activity and all participants were able to pass in fewer than three attempts. In the simulation survey, 64% of CRCs reported feeling “very competent” in screening and eligibility for eligible patients, 86% “very competent” in informed consent, 64% “very competent” in study drug administration/randomization, 50% “very competent” in baseline activities/sample collection, and 57% “very competent” in follow-up and AE/SAE tracking. This is further shown in Table 4.

Table 4: Simulation Survey Results

	Not at All Competent	Slightly Competent	Somewhat Competent	Very Competent
How competent did you feel you could screen for eligible patients?	0% (0)	0% (0)	36% (5)	64% (9)
How competent did you feel going through the informed consent process?	0% (0)	0% (0)	14% (2)	86% (12)
How competent did you feel with study drug administration and randomization?	0% (0)	0% (0)	36% (5)	64% (9)
How competent did you feel with sample collection?	0% (0)	0% (0)	50% (7)	50% (7)
How competent did you feel with AE/SAE tracking?	0% (0)	14% (2)	29% (4)	57% (8)

Discussion

We devised a risk-based, competency-focused training program combining the JTFCDs and the ICH E6(R2) risk assessment process into a study-specific program for PECARN CRCs. We combined these two approaches to address our previous finding that institutional onboarding processes did not adequately prepare PECARN CRCs to perform their jobs effectively. The risk assessment process helped identify moderate- to high-risk study procedures that could potentially impact study data or patient safety in a PECARN clinical trial. The staff training checklist helped direct the CRCs to the key risk areas *prior* to the training, and required them to identify potential problems in integrating the key study procedures at their own site.

We designed the training session to emphasize the moderate- and high-risk procedures both by using didactic lectures and mock scenarios. We felt “hands-on” scenarios combined with the lectures would help to instill confidence in the CRCs. Eligibility determination, obtaining parental permission, study drug administration, and sample collection were all determined to have higher than standard risk and elevated complexity, and were therefore integrated into the Staff Training Checklist and the study training session.

Finally, we implemented a study-specific simulation activity at each site that required CRCs to demonstrate competency in performing the moderate- to high-risk procedures as well as the activities in the JTFCDs. Importantly, the simulation activity required CRCs to demonstrate competence by successfully performing both standard skills representing the JTFCDs as well as the key procedures identified in the risk assessment.

Our results suggest that this focused approach helped CRCs feel competent in the high- to moderate-risk areas of the trial as well as in the standard areas of research. The risk-based approach combined with the JTFCDs resulted in a highly focused training session designed to increase CRC perceived competence as well as demonstrate competence in a study simulation activity. We suggest that this sort of measure is a critical piece of determining competence in perceived and actual performance, and recommend that other programs integrate similar programs.

While many CRCs felt “very competent” on most of the skills, there were CRCs who indicated they felt only “somewhat competent” on key study activities. It is difficult to distinguish whether those who felt “somewhat competent” were more modest in their self-evaluation, or whether that categorization reflects a perceived shortfall in knowledge.

CRCs’ perceived competency varied across the different areas of the survey. For example, 70% or more of CRCs perceived they were competent in informed consent, the ICH E6(R2) GCP guidelines, and the study drug administration in the competency survey, but fewer CRCs selected “very competent” for AE/SAE reporting and sample collection. This disparity could have been related to the amount of training time devoted to each topic, the topic’s complexity, or the baseline knowledge of each CRC.

We acknowledge that there are areas in which our training may have fallen short, and we will address the areas with lower perceived competence in our next training. We also noticed differences in perceived competency between the two surveys. Seventy percent of CRCs indicated they were “very competent” in determining the “appropriate study dose” in the competency survey, but only 64% indicated they were very competent in “study drug administration and randomization” in the simulation survey.

While we cannot make any statistical comparison nor conclusion between these two groups, we suggest the difference may be because an individual’s perception of competence does not always match their performance of a specific task. The variation in the wording of the questions could have contributed to this difference, or the time period in which the survey was administered may have impacted these responses.

Despite these differences, we are encouraged by the fact that most participants ranked their competence in the upper two categories (“very competent” and “somewhat competent”). Each CRC successfully passed the simulation activity by demonstrating competency in key study activities. This suggests that perception of competence is not an adequate predictor of performance, or that despite *demonstrating* competency in performing the task, CRCs may have lingering doubt about their own individual perceived competency, and thus the scores may never match the performance.

Limitations

Competence evaluations rely on self-report of the participants and are subjective. We did not know what the levels of perceived competency were before the CRCs completed the study training. The study simulation activities were conducted as was customary in each institution's Emergency Department and were not standardized. While we provided a study script and a standardized competency check-off form, the actual simulation activity may have varied among sites, and this could have affected results.

Another limitation is a difference between the number of participants in the competency survey (20) and the simulation survey (14)—because they are not identical, it is difficult to draw conclusions of relevant competency within both groups. We also realize that the options on the competency survey and the simulation survey (“not at all,” “slightly,” “somewhat,” and “very” competent) were not defined, and this could have resulted in different interpretations by the participants.

Conclusion

CRCs successfully demonstrated key study skills and reported feeling competent in key study activities after completing a risk-based, competency focused training program for a randomized clinical trial of severely injured children. A risk-based training program that incorporates JTFCs may lead to better performance of study procedures in a clinical trial. It will be beneficial to follow up with the participants to see if, after having enrolled study patients, they feel as though the training helped sustain their confidence.

References

1. Sonstein SA SJ, Li R, Jones CT, Silva H, Daemen E. 2014. Moving from compliance to competency: a harmonized core competency framework for the clinical research professional. *Clinical Researcher* 28(3):17–23. doi:10.14524/CR-14-00002R1.1. <https://acrpnet.org/crjune2014/>
2. The Pediatric Emergency Care Applied Research Network (PECARN): rationale, development, and first steps. *Acad Emerg Med* 2003;10(6):661–8. <https://pubmed.ncbi.nlm.nih.gov/12782530/>

3. Saunders J, Pimenta K, Zuspan S, Berent R, Herzog N, Jones C, Kline J, Kocher K, Robinson V, Thomas B, Stanley RM. 2017. Inclusion of the Joint Task Force Competency Domains in onboarding programs for clinical research coordinators: variations, enablers, and barriers. *Clinical Researcher* 31(6). <https://www.acrpnet.org/2017/12/12/inclusion-joint-task-force-competency-domains-onboarding-crcs/>
4. E6(R2) Good Clinical Practice: Integrated Addendum to ICH E6(R1)—Guidance for Industry. 2018. <https://www.fda.gov/media/93884/download>
5. Nishijima DK, VanBuren J, Hewes HA, Myers SR, Stanley RM, Adelson PD, et al. 2018. Traumatic injury clinical trial evaluating tranexamic acid in children (TIC-TOC): study protocol for a pilot randomized controlled trial. *Trials* 19(1):593.
6. Fisher KE, Martin M, McClain A, Stanley R, Saunders J, Lo C, et al. Nurse-driven simulations to prepare and educate for a clinical trial. *Clin Simul in Nursing* 28:35–8.

Acknowledgements

Research reported in this publication was supported by the National Heart, Lung, and Blood Institute (NHLBI) of the National Institutes of Health under Award Number R34HL135214. PECARN is supported by the Health Resources and Services Administration (HRSA) of the U.S. Department of Health and Human Services (HHS), in the Maternal and Child Health Bureau (MCHB), under the Emergency Medical Services for Children (EMSC) program through the following cooperative agreements: DCC-University of Utah, GLEMSCRN-Nationwide Children’s Hospital, HOMERUN-Cincinnati Children’s Hospital Medical Center, PEMNEWS-Columbia University Medical Center, PRIME-University of California at Davis Medical Center, CHaMP node-State University of New York at Buffalo, WPEMR-Seattle Children's Hospital, and SPARC-Rhode Island Hospital/Hasbro Children's Hospital. This information or content and conclusions are those of the authors and should not be construed as the official position or policy of, nor should any endorsements be inferred by HRSA, HHS, or the U.S. Government.

Additional support was provided by the Resource-Related Cooperative Agreement, National Center for Advancing Translational Science, 1U24TR001597 Utah Trial Innovation Center.

Jessica Fritter, MACPR, is a Clinical Research Administration Manager with Clinical Research Services at Nationwide Children’s Hospital, an Instructor for the Master of Clinical Research program at The Ohio State University, and lead author for this article.

Melissa Metheney, BSN, CCRC, is Program Director with the Data Coordinating Center at the University of Utah.

Sally Jo Zuspan, RN, MSN, is Director of Research with the Data Coordinating Center at the University of Utah and senior author for this article.

Clinical Researcher—June 2020 (Volume 34, Issue 6)

PEER REVIEWED

Navigating a Career as a Clinical Research Professional: Where to Begin?

Bridget Kesling, MACPR; Carolynn Jones, DNP, MSPH, RN, FAAN; Jessica Fritter, MACPR; Marjorie V. Neidecker, PhD, MEng, RN, CCRP



Those seeking an initial career in clinical research often ask how they can “get a start” in the field. Some clinical research professionals may not have heard about clinical research careers until they landed that first job. Individuals sometimes report that they have entered the field “accidentally” and were not previously prepared. Those trying to enter the clinical research field lament that it is hard to “get your foot in the door,” even for entry-level jobs and even if you have clinical research education. An understanding of how individuals

enter the field can be beneficial to newcomers who are targeting clinical research as a future career path, including those novices who are in an academic program for clinical research professionals.

We designed a survey to solicit information from students and alumni of an online academic clinical research graduate program offered by a large public university. The purpose of the survey was to gain information about how individuals have entered the field of clinical research; to identify facilitators and barriers of entering the field, including advice from seasoned practitioners; and to share the collected data with individuals who wanted to better understand employment prospects in clinical research.

Background

Core competencies established and adopted for clinical research professionals in recent years have informed their training and education curricula and serve as a basis for evaluating and progressing in the major roles associated with the clinical research enterprise.{1,2} Further, entire academic programs have emerged to provide degree options for clinical research,{3,4} and academic research sites are focusing on standardized job descriptions.

For instance, Duke University re-structured its multiple clinical research job descriptions to streamline job titles and progression pathways using a competency-based, tiered approach. This led to advancement pathways and impacted institutional turnover rates in relevant research-related positions.{5,6} Other large clinical research sites or contract research organizations (CROs) have structured their onboarding and training according to clinical research core competencies. Indeed, major professional organizations and U.S. National Institutes of Health initiatives have adopted the Joint Task Force for Clinical Trial Competency as the gold standard approach to organizing training and certification.{7,8}

Recent research has revealed that academic medical centers, which employ a large number of clinical research professionals, are suffering from high staff turnover rates in this arena, with issues such as uncertainty of the job, dissatisfaction with training, and unclear professional development and role progression pathways being reported as culprits in this turnover.{9} Further, CROs report a significant shortage of clinical research associate (CRA) personnel.{10} Therefore, addressing factors that would help novices gain initial jobs would address an important workforce gap.

Methods

This mixed-methods survey study was initiated by a student of a clinical research graduate program at a large Midwest university who wanted to know how to find her first job in clinical research. Current students and alumni of the graduate program were invited to participate in an internet-based survey in the fall semester of 2018 via e-mails sent through the program listservs of current and graduated students from the program's lead faculty. After the initial e-mail, two reminders were sent to prospective participants.

The survey specifically targeted students or alumni who had worked in clinical research. We purposefully avoided those students with no previous clinical research work experience, since they would not be able to discuss their pathway into the field. We collected basic demographic information, student's enrollment status, information about their first clinical research position (including how it was attained), and narrative information to describe their professional progression in clinical research. Additional information was solicited about professional organization membership and certification, and about the impact of graduate education on the acquisition of clinical research jobs and/or role progression.

The survey was designed so that all data gathered (from both objective responses and open-ended responses) were anonymous. The survey was designed using the internet survey instrument Research Electronic Data Capture (REDCap), which is a secure, web-based application designed to support data capture for research studies. REDCap provides an intuitive interface for validated data entry; audit trails for tracking data manipulation and export procedures; automated export procedures for seamless data downloads to common statistical packages; and procedures for importing data from external sources. { 11 }

Data were exported to Excel files and summary data were used to describe results. Three questions solicited open-ended responses about how individuals learned about clinical research career options, how they obtained their first job, and their advice to novices seeking their first job in clinical research. Qualitative methods were used to identify themes from text responses. The project was submitted to the university's institutional review board and was classified as exempt from requiring board oversight.

Results

A total of 215 survey invitations were sent out to 90 current students and 125 graduates. Five surveys were returned as undeliverable. A total of 48 surveys (22.9%) were completed. Because the survey was designed to collect information from those who were working or have worked in clinical research, those individuals (n=5) who reported (in the first question) that they had never worked in clinical research were eliminated. After those adjustments, the total number completed surveys was 43 (a 20.5% completion rate).

The median age of the participants was 27 (range 22 to 59). The majority of respondents (89%) reported being currently employed as clinical research professionals and 80% were working in clinical research at the time of graduate program entry. The remaining respondents had worked in clinical research in the past. Collectively, participants' clinical research experience ranged from less than one to 27 years.

Research assistant (20.9%) and clinical research coordinator (16.3%) were the most common first clinical research roles reported. However, a wide range of job titles were also reported. When comparing entry-level job titles of participants to their current job title, 28 (74%) respondents reported a higher level job title currently, compared to 10 (26%) who still had the same job title.

Twenty-four (65%) respondents were currently working at an academic medical center, with the remaining working with community medical centers or private practices (n=3); site management organizations or CROs (n=2); pharmaceutical or device companies (n=4); or the federal government (n=1).

Three respondents (8%) indicated that their employer used individualized development plans to aid in planning for professional advancement. We also asked if their current employer provided opportunities for professional growth and advancement. Among academic medical center respondents, 16 (67%) indicated in the affirmative. Respondents also affirmed growth opportunities in other employment settings, with the exception of one respondent working in government and one respondent working in a community medical center.

Twenty-five respondents indicated membership to a professional association, and of those, 60% reported being certified by either the Association of Clinical Research Professionals (ACRP) or the Society of Clinical Research Associates (SoCRA).

Open-Ended Responses

We asked three open-ended questions to gain personal perspectives of respondents about how they chose clinical research as a career, how they entered the field, and their advice for novices entering the profession. Participants typed narrative responses.

“Why did you decide to pursue a career in clinical research?”

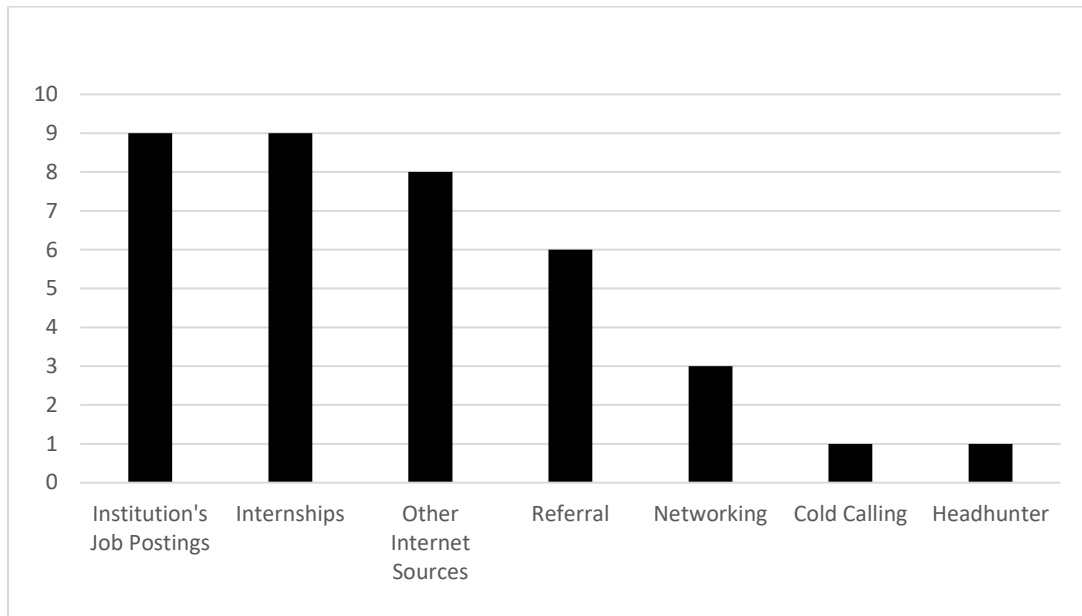
This question was asked to find out how individuals made the decision to initially consider clinical research as a career. Only one person in the survey had exposure to clinical research as a career option in high school, and three learned about such career options as college undergraduates. One participant worked in clinical research as a transition to medical school, two as a transition to a doctoral degree program, and two with the desire to move from a bench (basic science) career to a clinical research career.

After college, individuals either happened across clinical research as a career “by accident” or through people they met. Some participants expressed that they found clinical research careers interesting (n=6) and provided an opportunity to contribute to patients or improvements in healthcare (n=7).

“How did you find out about your first job in clinical research?”

Qualitative responses were solicited to obtain information on how participants found their first jobs in clinical research. The major themes that were revealed are sorted in Figure 1.

Figure 1: How First Jobs in Clinical Research Were Found



Some reported finding their initial job through an institution's job posting.

"I worked in the hospital in the clinical lab. I heard of the opening after I earned my bachelor's and applied."

Others reported finding about their clinical research position through the internet. Several did not know about clinical research roles before exploring a job posting.

"In reviewing jobs online, I noticed my BS degree fit the criteria to apply for a job in clinical research. I knew nothing about the field."

"My friend recommended I look into jobs with a CRO because I wanted to transition out of a production laboratory."

"I responded to an ad. I didn't really know that research could be a profession though. I didn't know anything about the field, principles, or daily activities."

Some of the respondents reported moving into a permanent position after a role as an intern.

“My first clinical job came from an internship I did in my undergrad in basic sleep research. I thought I wanted to get into patient therapies, so I was able to transfer to addiction clinical trials from a basic science lab. And the clinical data management I did as an undergrad turned into a job after a few months.”

“I obtained a job directly from my graduate school practicum.”

“My research assistant internship [as an] undergrad provided some patient enrollment and consenting experience and led to a CRO position.”

Networking and referrals were other themes that respondents indicated had a direct impact on them finding initial employment in clinical research.

“I received a job opportunity (notice of an opening) through my e-mail from the graduate program.”

“I was a medical secretary for a physician who did research and he needed a full-time coordinator for a new study.”

“I was recommended by my manager at the time.”

“A friend had a similar position at the time. I was interested in learning more about the clinical research coordinator position.”

“What advice do you have for students and new graduates trying to enter their first role in clinical research?”

We found respondents (n=30) sorted into four distinct categories: 1) a general attitude/approach to job searching, 2) acquisition of knowledge/experience, 3) actions taken to get a position, and 4) personal attributes as a clinical research professional in their first job.

Respondents stressed the importance of flexibility and persistence (general attitude/approach) when seeking jobs. Moreover, 16 respondents stressed the importance of learning as much as they could about clinical research and gaining as much experience as they could in their jobs,

encouraging them to ask a lot of questions. They also stressed a broader understanding of the clinical research enterprise, the impact that clinical research professional roles have on study participants and future patients, and the global nature of the enterprise.

“Apply for all research positions that sound interesting to you. Even if you don't meet all the requirements, still apply.”

“Be persistent and flexible. Be willing to learn new skills and take on new responsibilities. This will help develop your own niche within a group/organization while creating opportunities for advancement.”

“Be flexible with salary requirements earlier in your career and push yourself to learn more [about the industry's] standards [on] a global scale.”

“Be ever ready to adapt and change along with your projects, science, and policy. Never forget the journey the patients are on and that we are here to advance and support it.”

“Learning the big picture, how everything intertwines and works together, will really help you progress in the field.”

In addition to learning as much as one can about roles, skills, and the enterprise as a whole, advice was given to shadow or intern whenever possible—formally or through networking—and to be willing to start with a smaller company or with a lower position. The respondents stressed that novices entering the field will advance in their careers as they continue to gain knowledge and experience, and as they broaden their network of colleagues.

“Take the best opportunity available to you and work your way up, regardless [if it is] at clinical trial site or in industry.”

“Getting as much experience as possible is important; and learning about different career paths is important (i.e., not everyone wants or needs to be a coordinator, not everyone goes to graduate school to get a PhD, etc.).”

“(A graduate) program is beneficial as it provides an opportunity to learn the basics that would otherwise accompany a few years of entry-level work experience.”

“Never let an opportunity pass you up. Reach out directly to decision-makers via e-mail or telephone—don't just rely on a job application website. Be willing to start at the bottom. Absolutely, and I cannot stress this enough, [you should] get experience at the site level, even if it's just an internship or [as a] volunteer. I honestly feel that you need the site perspective to have success at the CRO or pharma level.”

Several personal behaviors were also stressed by respondents, such as knowing how to set boundaries, understanding how to demonstrate what they know, and ability to advocate for their progression. Themes such as doing a good job, communicating well, being a good team player, and sharing your passion also emerged.

“Be a team player, ask questions, and have a good attitude.”

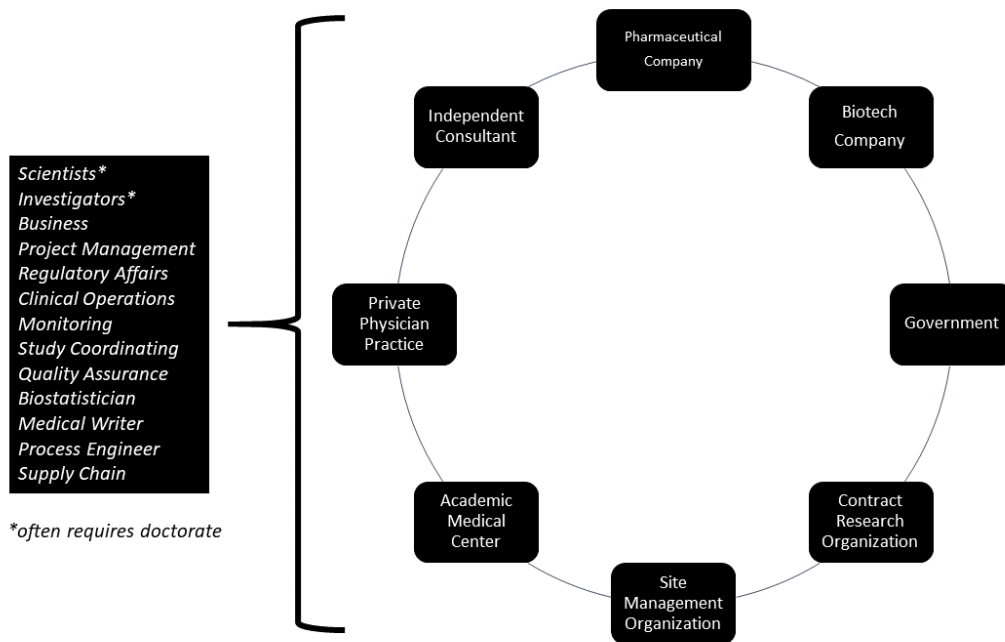
“Be eager to share your passion and drive. Although you may lack clinical research experience, your knowledge and ambition can impress potential employers.”

“[A] HUGE thing is learning to sell yourself. Many people I work with at my current CRO have such excellent experience, and they are in low-level positions because they didn't know how to negotiate/advocate for themselves as an employee.”

Discussion

This mixed-methods study used purposeful sampling of students in an academic clinical research program to gain an understanding of how novices to the field find their initial jobs in the clinical research enterprise; how to transition to a clinical research career; and how to find opportunities for career advancement. There are multiple clinical research careers and employers (see Figure 2) available to individuals working in the clinical research enterprise.

Figure 2: Employers and Sample Careers



Despite the need for employees in the broad field of clinical research, finding a pathway to enter the field can be difficult for novices. The lack of knowledge about clinical research as a career option at the high school and college level points to an opportunity for broader inclusion of these careers in high school and undergraduate curricula, or as an option for guidance counselors to be aware of and share with students.

Because most clinical research jobs appear to require previous experience in order to gain entry, novices are often put into a “Catch-22” situation. However, once hired, upward mobility does exist, and was demonstrated in this survey. Mobility in clinical research careers (moving up and general turnover) may occur for a variety of reasons—usually to achieve a higher salary, to benefit from an improved work environment, or to thwart a perceived lack of progression opportunity.{9}

During COVID-19, there may be hiring freezes or furloughs of clinical research staff, but those personnel issues are predicted to be temporary. Burnout has also been reported as an issue among study coordinators, due to research study complexity and workload issues.{12} Moreover, the

lack of individualized development planning revealed by our sample may indicate a unique workforce development need across roles of clinical research professionals.

This survey study is limited in that it is a small sample taken specifically from a narrow cohort of individuals who had obtained or were seeking a graduate degree in clinical research at a single institution. The study only surveyed those currently working in or who have a work history in clinical research. Moreover, the majority of respondents were employed at an academic medical center, which may not fully reflect the general population of clinical research professionals.

It was heartening to see the positive advancement in job titles for those individuals who had been employed in clinical research at program entry, compared to when they responded to the survey. However, the sample was too small to draw reliable correlations about job seeking or progression.

Conclusion

Although finding one's first job in clinical research can be a lengthy and discouraging process, it is important to know that the opportunities are endless. Search in employment sites such as Indeed.com, but also search within job postings for targeted companies or research sites such as biopharmguy.com (see Table 1). Created a LinkedIn account and join groups and make connections. Participants in this study offered sound advice and tips for success in landing a job (see Figure 3).

Table 1: Sample Details from an Indeed.Com Job Search

Position	Company	Minimum Qualifications
Clinical Research Patient Recruiter	PPD	Bachelor's degree and related experience
Clinical Research Assistant	Duke University	Associate degree
Clinical Trials Assistant	Guardian Research Network	Bachelor's degree and knowledge of clinical trials
Clinical Trials Coordinator	Advarra Health Analytics	Bachelor's degree
Clinical Research Specialist	Castle Branch	Bachelor's degree and six months in a similar role
Clinical Research Technician	Rose Research Center, LLC	Knowledge of Good Clinical Practice and experience working with patients

Clinical Research Lab Coordinator Project Specialist	Coastal Carolina Research Center WCG	One year of phlebotomy experience Bachelor's degree and six months of related experience
Data Coder	WCG	Bachelor's degree or currently enrolled in an undergraduate program

Note: WCG = WIRB Copernicus Group

Figure 3: Twelve Tips for Finding Your First Job

- Seek out internships and volunteer opportunities
- Network, network, network
- Be flexible and persistent
- Learn as much as possible about clinical research
- Consider a degree in clinical research
- Ask a lot of questions of professionals working in the field
- Apply for all research positions that interest you, even if you think you are not qualified
- Be willing to learn new skills and take on new responsibilities
- Take the best opportunity available to you and work your way up
- Learn to sell yourself
- Sharpen communication (written and oral) and other soft skills
- Create an ePortfolio or LinkedIn account

Being willing to start at the ground level and working upwards was described as a positive approach because moving up does happen, and sometimes quickly. Also, learning soft skills in communication and networking were other suggested strategies. Gaining education in clinical research is one way to begin to acquire knowledge and applied skills and opportunities to network with experienced classmates who are currently working in the field.

Most individuals entering an academic program have found success in obtaining an initial job in clinical research, often before graduation. In fact, the student initiating the survey found a position in a CRO before graduation.

References

1. Sonstein S, Seltzer J, Li R, Jones C, Silva H, Daemen E. 2014. Moving from compliance to competency: a harmonized core competency framework for the clinical research professional. *Clinical Researcher* 28(3):17–23. doi:10.14524/CR-14-00002R1.1. <https://acrpnet.org/crjune2014/>

2. Sonstein S, Brouwer RN, Gluck W, et al. 2018. Leveling the joint task force core competencies for clinical research professionals. *Therap Innov Reg Sci*.
3. Jones CT, Benner J, Jelinek K, et al. 2016. Academic preparation in clinical research: experience from the field. *Clinical Researcher* 30(6):32–7. doi:10.14524/CR-16-0020. <https://acrpnnet.org/2016/12/01/academic-preparation-in-clinical-research-experience-from-the-field/>
4. Jones CT, Gladson B, Butler J. 2015. Academic programs that produce clinical research professionals. *DIA Global Forum* 7:16–9.
5. Brouwer RN, Deeter C, Hannah D, et al. 2017. Using competencies to transform clinical research job classifications. *J Res Admin* 48:11–25.
6. Stroo M, Ashfaw K, Deeter C, et al. 2020. Impact of implementing a competency-based job framework for clinical research professionals on employee turnover. *J Clin Transl Sci*.
7. Calvin-Naylor N, Jones C, Wartak M, et al. 2017. Education and training of clinical and translational study investigators and research coordinators: a competency-based approach. *J Clin Transl Sci* 1:16–25. doi:10.1017/cts.2016.2
8. Development, Implementation and Assessment of Novel Training in Domain-based Competencies (DIAMOND). Center for Leading Innovation and Collaboration (CLIC). 2019. <https://clic-ctsa.org/diamond>
9. Clinical Trials Talent Survey Report. 2018. <http://www.appliedclinicaltrials.com/node/351341/done?sid=15167>
10. Causey M. 2020. CRO workforce turnover hits new high. *ACRP Blog*. <https://acrpnnet.org/2020/01/08/cro-workforce-turnover-hits-new-high/>
11. Harris PA, Taylor R, Thielke R, Payne J, Gonzalez N, Conde JG. 2009. Research electronic data capture (REDCap): a metadata-driven methodology and workflow process for providing translational research informatics support. *J Biomed Inform* 42:377–81.
12. Gwede CK, Johnson DJ, Roberts C, Cantor AB. 2005. Burnout in clinical research coordinators in the United States. *Oncol Nursing Forum* 32:1123–30.

A portion of this work was supported by the OSU CCTS, CTSA Grant #UL01TT002733.

Bridget Kesling, MACPR, (Kesling.9@osu.edu) is a Project Management Analyst with IQVIA in Durham, N.C.

Carolynn Jones, DNP, MSPH, RN, FAAN, (Jones.5342@osu.edu) is an Associate Professor of Clinical Nursing at The Ohio State University College of Nursing, Co-Director of Workforce Development for the university's Center for Clinical and Translational Science, and Director of the university's Master of Clinical Research program.

Jessica Fritter, MACPR, (Fritter.5@osu.edu) is a Clinical Research Administration Manager at Nationwide Children's Hospital and an Instructor for the Master of Clinical Research program at The Ohio State University.

Marjorie V. Neidecker, PhD, MEng, RN, CCRP, (Neidecker.1@osu.edu) is an Assistant Professor of Clinical Nursing at The Ohio State University Colleges of Nursing and Pharmacy.

HOME STUDY

THE MORE THINGS CHANGE...

Article 1: Impact of a Risk-Based, Study-Specific Training Program on Research Coordinator Competency

LEARNING OBJECTIVE

After reading this article, the participant should be able to describe the reasoning behind and design of a targeted, competency-based training program focused on moderate to high risks in a specific study, and to elaborate on its results on levels of competency and performance in clinical research coordinators.

DISCLOSURE

Jessica Fritter, MACPR; Melissa Metheney, BSN, CCRC; Sally Jo Zuspan, RN, MSN: *Nothing to disclose*

- 1. Prior to the training program described in this article, what was the general attitude of CRCs in the PECARN regarding their on-the-job performance?**
 - A. Most of the CRCs felt more than competent to perform their jobs adequately.
 - B. Most of the CRCs felt reasonably competent to perform their jobs adequately.
 - C. Most of the CRCs felt less than competent to perform their jobs adequately.
 - D. Most of the CRCs felt neither competent nor incompetent to perform their jobs adequately.

- 2. How should high- and moderate-risk study activities be addressed in a trial?**
 - A. Through post-trial monitoring audits.
 - B. Through a risk mitigation plan.
 - C. Through Clinical Trial Agreements.
 - D. Through the informed consent process.

- 3. The training program for CRCs combined input from which two entities?**
 - A. The Center for Drug Evaluation and Research and the American Medical Association.
 - B. The International Council for Harmonization and the Joint Task Force Competency Domains.
 - C. The PECARN Institutional Review Board and the Association of Clinical Research Professionals.
 - D. The Association for the Accreditation of Human Research Protection Programs and Public Responsibility in Medicine and Research.

4. What were the two main elements of the CRC training program?

- A. A study training plan and a simulation activity.
- B. An online research ethics course and mentoring.
- C. Pre- and post-study evaluations of CRCs by the study PI.
- D. Personality inventories and random tests of job skill levels.

5. In-person CRC training covered which of the following study aspects cited in the article?

- A. Disease history, randomization, treatment blinding
- B. Withdrawal of consent, non-compliance, adverse events
- C. Study budgeting, patient billing, sponsor communications
- D. Protocol, enrollment, basic research competencies

6. According to the article, the informed consent process falls under which competency domain?

- A. Site and Study Management
- B. Ethical and Participant Safety Considerations
- C. Communications and Teamwork
- D. Scientific Concepts and Research Design

7. Study-specific simulations of study activities that the CRCs were challenged with include which of the following?

- A. Research budget preparation, study drug procurement/storage, patient attitudinal surveys
- B. Sponsor query resolution, database input/management techniques, study drug compliance/destruction
- C. Informed consent, study drug administration/randomization, and baseline activities/sample collection
- D. Principal investigator communications, monitoring visits/preparations, regulatory audit SOPs

8. How many of the CRCs reported feeling “somewhat competent” in understanding and reporting safety and AE/SAE issues after the training?

- A. 20%
- B. 30%
- C. 40%
- D. 50%

9. Following the simulation activity, how many of the CRCs felt “very competent” with sample collection?

- A. 20%
- B. 30%
- C. 40%
- D. 50%

- 10. Which of the following is noted as a limitation of the competency and simulation surveys?**
- A. No statistical comparison nor conclusion can be made between the two groups.
 - B. They were completed too far apart to be of any informative value for the authors.
 - C. The survey respondents did not appear to take the questions seriously enough.
 - D. Too many surveys were left too incomplete for proper analysis of trends to be performed.

Article 2: Navigating a Career as a Clinical Research Professional: Where to Begin?

LEARNING OBJECTIVE

After reading this article, the participant should be able to describe typical scenarios of how individuals enter the clinical research field, and to summarize the results of a related survey of students and alumni of an online academic clinical research graduate program offered by a large public university.

DISCLOSURE

Bridget Kesling, MACPR;Carolynn Jones, DNP, MSPH, RN, FAAN; Jessica Fritter, MACPR; Marjorie V. Neidecker, PhD, MEng, RN, CCRP: *Nothing to disclose*

- 11. Which of the following is mentioned as an example of an initiative at Duke University based on the concept of clinical research core competencies?**
- A. Restructuring the university's office for outreach to study sponsors.
 - B. Accelerating the onboarding of new study coordinators and assistants.
 - C. Streamlining clinical research job titles and progression pathways.
 - D. Eliminating annual job performance reviews for long-term staff.
- 12. Which of the following is mentioned as a particular challenge for conducting clinical research at academic medical centers?**
- A. Excessive overhead fees.
 - B. High staff turnover rates.
 - C. Low patient engagement.
 - D. Decreased need for trials.
- 13. The survey described in the article excluded which of the following groups of people?**
- A. Anyone with no previous clinical research work experience.
 - B. Research veterans who had ever participated as a trial subject.
 - C. Brand new research team members still in training mode.
 - D. Principal investigators who have never been certified as such.

- 14. How many of the survey respondents were currently working at a higher level job title than what had been their entry-level title?**
- A. 14%
 - B. 34%
 - C. 54%
 - D. 74%
- 15. How did respondents who did not know about clinical research career opportunities until after college learn of the field?**
- A. Through recruiting agencies for academic medical centers.
 - B. From participating in trials as volunteers.
 - C. By accident or through someone they met.
 - D. From subscribing to ACRP publications.
- 16. Respondents stressed the importance of which qualities for first-time job seekers?**
- A. Certification and professionalism.
 - B. Flexibility and persistence.
 - C. Objectivity and open-mindedness.
 - D. Honesty and modesty.
- 17. Respondents advocated willingness to start work with which kind of company for novices?**
- A. Smaller
 - B. Larger
 - C. Non-profit
 - D. International
- 18. Which clinical research positions are noted as often requiring a doctorate?**
- A. Project management and quality assurance.
 - B. Clinical operations and supply chain.
 - C. Scientists and investigators.
 - D. Medical writer and regulatory affairs.
- 19. The authors suggest broader inclusion of information about clinical research careers in what settings?**
- A. Community job fairs and marketing campaigns.
 - B. Study sponsors' open houses and publications.
 - C. Hospitals' human resources offices and outreach.
 - D. High school and undergraduate curricula.
- 20. Research study complexity and workload are noted as causing which of the following issues among study coordinators?**
- A. Fraud
 - B. Burnout
 - C. Negligence
 - D. Lawsuits