Clinical Researcher
December 2017
HOME STUDY TEST
Your Research Career Advancement: Planned or Pushed?

Earn 3.0 Continuing Education Credits
Three articles from the online December 2017 issue of Clinical Researcher (see https://www.acrpnet.org/resources/clinical-researcher/) have been selected as the basis for a Home Study test that contains 30 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 December 31, 2018. This activity is anticipated to take three hours. Answers must be submitted using the electronic answer form online (members only, $60). 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.

CONTINUING EDUCATION INFORMATION
The Association of Clinical Research Professionals (ACRP) is an approved provider of nursing and clinical research continuing education credits.

Contact Hours
The Association of Clinical Research Professionals (ACRP) provides 3.0 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-2017-HMS-012)

Continuing Nursing Education
The California Board of Registered Nursing (Provider Number 11147) approves the Association of Clinical Research Professionals (ACRP) as a provider of continuing nursing education. This activity provides 3.0 nursing education credits. (Program Number 11147-2017-HMS-012)

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 ADVISORY BOARD
Jerry Stein, PhD (Chair)
Paula Smailes, RN, MSN, CCRC, CCRP (Vice Chair)
Suheila Abdul-Karrim, CCRA, CCRT (Training and Development Liaison)
Victor Chen
Fraser Gibson, CCRA, CCRP
Gregory Hale, MD, CPI
Stuart Horowitz, PhD, MBA
Stefanie La Manna, PhD, ARNP, FNP-C
Jamie Meseke, MSN, CCRA
Christina Nance, PhD, CPI
Ernest Prentice, PhD (Association Board of Trustees Liaison)
Grannum Sant, MD, BCh, BAO (Hons.), MA, FRCS, FACS
Shirley Trainor-Thomas, MHS
Heather Wright, BS, BA:
Nothing to Disclose

ACRP STAFF/VOLUNTEERS
James Michael Causey (Editor-in-Chief)
Gary W. Cramer (Managing Editor)
Karen Bachman
Jan Kiszko, MD
Jo Northcutt
Deepti Patki, MS, CCRC
Barbara van der Schalie
Christine Streaker:
Nothing to Disclose
In August 2016, the American Nurses Association (ANA) formally recognized clinical research nursing as a specialty within the nursing profession. Clinical research nurses are specially trained nurses responsible for safeguarding research subjects, while maintaining the integrity of the research protocol in outpatient and inpatient settings with subjects who are healthy, acute, or chronically ill.¹

The International Association of Clinical Research Nurses (IACRN) is a professional organization whose purpose furthers the cause of these nurses by defining, validating, and advancing this specialty practice by supporting the professional development of registered nurses who impact the care of clinical research participants.² To further define clinical research nursing, the IACRN and the ANA joined forces to develop the scope and standards of practice for research nurses’ efforts to gain the skills to provide safe, accurate, efficient, and ethical care that complies with research regulations.

Professional Advancement in Nursing

“Clinical ladders” are commonly designed as professional development tools to reward nurses for education and certification, research, clinical skills, and leadership.³ The idea behind clinical ladder programs stems from Patricia Benner’s “novice to expert” theory, which centers around the competence of the nurse through stages: novice, advanced beginner, competent, proficient, and expert.⁴

These programs offer a means for the bedside or staff nurse to advance in the profession. Nursing managers and administration can use ladder programs a means to retain nurses, increase their competency and satisfaction, and increase quality of patient care delivery. Progression up the clinical career ladder is typically conditional upon the nurse meeting defined criteria of clinical excellence, skills and competence, professional expertise, and educational attainment.⁵

The American Nurses Credentialing Center (ANCC) Magnet Recognition Program® is considered to be one of the international gold standards for quality in healthcare organizations.⁶ Magnet organizations are known for their superior nursing processes and quality patient care, which ANCC tout as ultimately leading to high levels of safety, quality, and
patient satisfaction. The idea behind magnet status is that these organizations can attract and, perhaps more importantly, retain quality nurses.

There are five Magnet Model components that organizations must meet to achieve this designation. These include transformational leadership; structural empowerment; exemplary professional practice; new knowledge, innovation, and improvements; and empirical quality results.\(^7\) Some institutions employ clinical ladder models in the three different fields of clinical practice, nursing management, and nursing education.\(^8\) The magnet components can be used as the guide for clinical ladders.

Being designated as a magnet hospital means attracting and retaining excellent nurses. Having clinical ladder programs for nurses at a magnet hospital increases this “magnetizing” effect by rewarding nurses with professional advancement at the bedside, recognition from peers and nursing leadership, and (often) financial rewards. Clinical ladder nurses are empowered to make decisions at the bedside, operating at the top of their nursing license and further improving the magnet effect.

While these programs are common outside the clinical research milieu, they are less commonly thought of within the clinical research setting. However, clinical ladders can be adequately transferred to this nursing specialty to serve as a means for career advancement that can ultimately have a positive impact on both research subjects and the research organization.

The purpose of this paper is to overview the experience of a clinical ladder program for clinical research nurses at a federally funded clinical research center based within the academic medical center for which the authors work.

**Clinical Research Centers**

In 1960, the National Institutes of Health (NIH) established General Clinical Research Centers (GCRC) with funding from the National Center for Research Resources. These are known for providing infrastructure and resources to support career development opportunities.\(^9\) In 2006, the funding structure was changed by the NIH, whose goal was to promote basic and clinical research, with subsequent translation to practice via the NIH-funded Clinical and Translational Science Awards (CTSA) program. This change in funding structure led to many centers renaming their GCRCs.

Inpatient centers that are part of the CTSA program are staffed by multidisciplinary teams including physicians and PhD investigators, administrators, nurse managers, nurse practitioners, staff nurses, dietitians, lab personnel, and medical technicians. The clinical research nurses serve as the core resource for these centers, and must execute multiple research protocols in this environment along with data and specimen collection using good clinical practices (GCPs). The clinical research nurse is responsible for moving research protocols from concept to reality at the bedside, while ensuring each encounter is safe and accurate for research participants and accurate for the principal investigators per the approved protocols.
Duties of clinical research nurses are highly varied from center to center, depending on the particular research emphases of each center. Duties may include, for example, extensive inpatient pharmacokinetics with monitoring for side effects and changes in the participants’ condition, simple sample collections, conscious sedation, biopsies, and insulin clamping procedures. Research nurses must be prepared to encounter many different populations with a variety of conditions, including rare diseases and first-in-human agents.

The research nurse is constantly learning new skills while building on prior knowledge from studies initiated in the past. The research nurse is integral to maintaining safety and order within protocol requirements, while promoting retention of the participant through excellent bedside care and supporting the volunteer nature of research studies.

Clinical Ladder Benefits…

...to Clinical Research Centers and Organizations

Some of the primary reasons for organizations to use a ladder program include staff retention, productivity, and job satisfaction. As this concept is applied to clinical research programs employing research nurses, its value continues to lie in the ability to offer professional advancement.

The clinical research center at the authors’ organization encourages clinical research staff nurses to participate in the institution’s clinical ladder program. When nurses participate, it allows the healthcare system to recognize clinical nurses, highlighting their advancement and accomplishments. When clinical research nurses contribute to the quality of the center, it in turn becomes a reflection of the organization and enhances research participants’ experiences.

Research nurses who are active in a clinical ladder program contribute to the different complex systems of the center by actively engaging in quality improvement, participant satisfaction and safety, and staff engagement. Being a part of the clinical ladder program elevates research nurses to increased levels of involvement in all of these areas and, in turn, helps engage peers and increases professionalism within the unit. Involvement in unit initiatives is expected and supported for clinical research nurses from those working at the bedside to the top nursing leadership levels in the institution. Importantly, nurses can remain at the bedside with participants while still advancing in the professional role of nursing at the institution.

Clinical research nurses in ladder programs offer fresh ideas for problem-solving and engagement of the team by helping to move through issues to reach resolution. One example in research is related to policies and procedures. Since many clinical research centers have unique activities that may not be institutionally recognized through standard hospital policies, the nurse in a clinical ladder program can be helpful in developing these unit-based policies.

For example, the use of peripheral IVs for frequent blood sampling has been a standard practice around the world at research centers for many decades, but most institutions do not support this activity in standard bedside practices. However, research participants might not be willing to
participate in research if they are required to endure venipuncture every 10 minutes for a 10-hour research study. For this reason, developing unit-based policies are important to research units.

The clinical ladder nurse can be helpful in this process by reviewing the literature related to the topic, gathering data on policies from other research centers or research GCP guidelines, writing the policy based on institutional guidelines, ensuring peer review on the unit, and finally, getting approval for the policy from administration so the policy can be put into practice. Not only does this help the unit, but it innately increases the engagement of the clinical ladder nurse and her peers.

The nurse participating in a clinical ladder program also promotes the professionalism required for increases in research participant satisfaction scores. The clinical ladder nurse is on the front line with the research participant, noting trends with different populations and engaging in safety reviews on a regular basis. This is helpful in monitoring metrics and noting if there are immediate issues with different research populations related to both satisfaction and safety.

Because the clinical ladder nurse is on the front line with the research participants, this can help support positive satisfaction scores and healthy outcomes. The authors have found that on their unit, high patient satisfaction scores may be related to this program. In the last year, more than 96% of research participants surveyed in the clinical research center reported having a positive experience with research study participation.

Further, having a nurse involved in clinical ladder promotes staff engagement, as the nurse becomes a positive change agent for the unit. A clinical ladder nurse tends to be fully committed to new processes, and typically is active with new initiatives. This may be related to the personal goals and outcomes that are required when progressing through the different clinical ladder levels. Nurses in the authors’ unit have engaged in quality improvement initiatives and have presented the outcomes at international research conferences via poster presentations.

...to Clinical Research Nurses

There are many reasons why a clinical research nurse should participate in a clinical ladder program for career advancement. One of the most significant is that it creates the opportunity to advance the nurse’s skills and career, while simultaneously allowing the nurse to stay at the bedside.

Research nurses in the authors’ clinical research center continue to provide direct patient care, and can use ladder programs to positively impact their patients by having ownership in improving the quality of patient care. This can be achieved by staying current with practice and doing literature searches, then subsequently incorporating evidenced-based techniques into practice. This may also lead to research nurses publishing and contributing to the evidence in clinical research.

Engaging in a clinical ladder program may also serve as a starting point for nurses who later want to advance in clinical research management. The skills acquired as part of the ladder program can be utilized in leadership positions involving project management, team building, supervisor roles, process improvement, and unit outcomes.
Certification can also be a means to advance up the clinical ladder. Clinical research certifications from professional organizations and their ongoing continuing education opportunities are encouraged by nursing and research administration. Research nurses can be offered time off to complete projects. Certification is a means of validating cognitive knowledge and continued competency—as recommended by the Institute of Medicine—and the most commonly cited reason for attaining certification is public safety. {3}

Finally, the most enticing benefit of clinical ladders can be increased pay. As clinical research nurses continue to advance up the ladder, this can contribute to more recognition, and with that comes monetary compensation. Clinical research nurse achievement through clinical ladder programs can be further evaluated annually and compensated accordingly.

Conclusion

Clinical ladder programs have been utilized as a competitive marketing strategy in times of nursing turnover and shortage, and have delivered proven impacts on the main stakeholders in healthcare: patients, employers, and nurses. {3} Clinical research programs that employ nurses can reap the benefits of clinical ladders, as nurses positively impact the quality of research-related patient care and data collected for study protocols. Having professional development programs like those involving clinical ladders in place encourages employee growth while showing organizational investment in nurses’ careers.

References

Paula Smailes, MSN, RN, CCRC, CCRP, (paula.smailes@osumc.edu) is a member of the ACRP Editorial Advisory Board, a senior training and optimization analyst for clinical research at The Ohio State University Wexner Medical Center, and a visiting professor with Chamberlain College of Nursing.

Holly Bookless, BSN, RN-BC, (holly.bookless@osumc.edu) is the nurse manager for the Clinical Research Center at The Ohio State University Wexner Medical Center.

Carrie Blumenuer, BSN, RN, is a research nurse for the Clinical Research Center at The Ohio State University Wexner Medical Center.
Recruit, Train, and Retain the Best: The Implementation of a Competency-Based Clinical Research Workforce Initiative

Rebecca Namenek Brouwer, MS; Deborah Hannah, BS; Christine Deeter, BS; Betsy Hames, JM; Denise Clutter Snyder, MS, LDN, RD

[DOI: 10.14524/CR-17-0040]

Bringing scientific discoveries to bear as safely and efficiently as possible is the goal of those involved in clinical research. To accomplish this, a skilled and stable workforce is critical—this means retaining staff who understand best practices, regulations, and how best to get things done. With today’s tight labor market, however, attracting the best and brightest to the profession of clinical research may be as challenging as retaining skilled employees.

Academic medical centers (AMCs) may experience particular challenges in recruiting high-quality staff, given the general decline of clinical research activities in this venue. Therefore, it’s important to create a clinical research workforce system within AMCs that appeals to potential job candidates as well as valuable incumbents, and that serves an ever-changing industry by emphasizing and rewarding development of specific competencies.

This paper describes an initiative that created a competency-based staffing structure at an AMC to provide, or at least encourage, the following:

- Standardized research roles
- A consistent approach to hiring and evaluating employees
- Advancement opportunities that rely on demonstrated competencies
- A transparent pathway for career growth and skill development
This workforce initiative was funded in part by an institutional Clinical and Translational Science Award (CTSA) grant from the National Institutes of Health (NIH) (UL1TR001117) to Duke University Medical Center. As such, it is the authors’ desire to share their experiences with others who may benefit from the work.

**Background**

Most adults need to work to earn a living; however, each individual has his or her own reasons for being attracted to, and remaining at, a particular job. This likely comes down to what motivates them, and many theories provide explanations for how this affects employee behavior.\(^2\)

Champagne and McAfee\(^3\) offered an employee motivational theory that listed five important aspects of satisfying employee needs: physiological, security (economic, psychological, etc.), affiliation (encouraging social interaction), esteem (job challenge), and self-actualization. These needs are based on the well-known hierarchy of needs, articulated by Abraham Maslow.\(^4\)

Meanwhile, the equity theory of motivation, determined by John Stacey Adams,\(^5\) invites additional factors that motivate employees. Here, staff motivation is dictated by whether they think what they are putting into a job relates to what they get out of it. Similarly, it is important that what a staff member gets out of the job is the same as his or her colleague—fair, consistent treatment is key to the equity theory.

To build and maintain a clinical research workforce within an AMC setting, Duke employed strategies to affect motivation at several levels. In this article, the authors explain the various components of the workforce initiative, which aimed to recruit, train, and retain valuable staff and bolster professionalism in clinical research support.

**Setting Up a Successful System**

Since July 2014, Duke has been working on professionalizing its clinical research workforce via a comprehensive initiative that involves many elements (see Figure 1 for a timeline of related activities).\(^6,7\) At its core, the initiative utilizes core competencies, developed by the Joint Task
The eight competency domains are: (1) Scientific Concepts and Research Design, (2) Ethical and Participant Safety Considerations, (3) Medicines Development and Regulation, (4) Clinical Trial Operations (GCPs), (5) Study and Site Management, (6) Data Management and Informatics, (7) Leadership and Professionalism, and (8) Communication and Teamwork. The work was undertaken by the Clinical Research Professionals Working Group (CRPWG), comprised of staff from Duke’s School of Medicine, the Duke Office of Clinical Research, and the university’s Human Resources and Rewards and Recognition units.

Importantly, this initiative was heavily supported by leadership within the School of Medicine and the Human Resources unit, and it has had implications throughout the institution.

**Standardizing Research Roles**

The standardizing of research roles was made possible by the development of competency-based job descriptions and incumbent alignment with those job descriptions. The number of job classifications held by clinical research staff at Duke had become difficult to manage and impossible to track. In order to create consistency and standardization across the institution, the CRPWG aimed to consolidate and simplify the number of clinical research job classifications. As a result of this project, the number of classifications was reduced from approximately 80 to 12.

A tool was created to assess the current job duties and competencies of clinical research staff at Duke. The competencies were founded in the work done by the aforementioned JTFCTC, and were tracked in alignment with an initiative undertaken by the 61 institutions participating in the NIH CTSA program at the time.

Each staff member was asked to complete a survey tool, designed for collection in REDCap™ (Research Electronic Data Capture; https://www.project-redcap.org), based on the job duties and level of identified competencies. The staff member’s manager reviewed the tool, then validated and altered as needed the responses based upon his or her assessment of the employee’s job duties and level of competency.
The answers provided by the staff member and manager were assessed by committee, in conjunction with review of the staff member’s CV and job description. The job classification that was deemed the “best fit” was provided to the leadership of the staff member’s research unit to ensure there were no major concerns regarding the position identified. More than 700 research professionals were mapped into these new classifications in two distinct waves.

**Consistent Hiring Practices**

The competencies that were utilized to map each of the incumbents into their new job classifications were modified for use in a REDCap™ tool for new hires. The survey requires hiring managers to answer a series of questions based on the competencies needed to meet the requirements of the open position. Outcomes of the survey are then analyzed by a group of subject matter experts to provide the job classification that most closely aligns with the position being discussed.

Once the best fit has been identified, the results are recorded in a database and a position-specific job description is sent to the hiring manager. Communication and collaboration with the Human Resources unit ensures all positions that may fit into one of the 12 clinical research job classifications are routed through the survey tool. By utilizing this systematic method, the time to classify and post a position has been reduced significantly.

**Tier Advancement**

More than 40 competencies for staff in these tiered positions were leveled into four categories—"fundamental,” “skilled,” “advanced,” and “expert.” Multimodal, standardized assessments were developed for each competency, to determine the candidate’s level of skill/knowledge. Core, required competencies were identified for each role. Points were assigned for each level, and the accumulated point total determines advancement to the next tier. (It is important to note that competencies in the domain of Leadership and Professionalism play a key role.)

Through the tier advancement process, staff are able to clearly see opportunities for growth and development. This relies on the staff being able to exhibit competency in the skills required to
perform their job. Staff are evaluated on these competencies by completing the previously mentioned assessments.

While an employee and his or her manager can select from several competencies, the Leadership and Professionalism competencies are required in order to progress. This fosters a sense of collaboration, professional growth, and innovation throughout the clinical research community.

The tools developed for the tier advancement process can be modified and used for training and onboarding purposes. The utilization of these tools for new hires creates consistency and efficiency across a variety of therapeutic areas of research and enhances a culture of professionalism.

While Duke has done much to professionalize its workforce, additional initiatives are in the planning stages, which will allow the institution to continue to build upon the competency model created. An example of this is that each employee who completes a competency assessment will have access to an individualized profile that reflects areas of strength within each domain. This can serve as part of an employee’s portfolio, and can be shared within the institution, as the assessments are consistent across units.

Portfolios may provide other AMCs information about research capability for staff who need to relocate and wish to continue their work at the same level. In addition, the hope is to take the competencies for each job classification and weave them into Duke’s clinical research training program and performance management system. By continuing to harmonize the expectations of managers across units, the institution aims to ensure consistent professional standards.

**Discussion**

This project was a significant undertaking, with regard to both time and money. Numerous staff and stakeholders were involved across the institution over several years. A core group of individuals were paid for the effort they devoted to operationally administer this initiative, but countless others volunteered their time to make it possible.
Many champions across the institution socialized the idea that the provision of career development opportunities to research professionals aims to positively affect not only individual staff, but also the institution and clinical research at large. There was some resistance to change, and concern about the financial impact shouldered by individual departments and research investigators. However, the strong commitment from the School of Medicine, Duke University Human Resources, and the research community in general made this project possible.

Stakeholder engagement in a project of this magnitude is absolutely necessary for success. The faculty were involved through their participation in an assembled Faculty Advisory Committee representing a number of clinical department disciplines, and are actively conducting their own research supported by diverse clinical research professional support teams. Their input and willingness to involve their staff in the “pilot” phase was critical.

The managers of the staff involved were also deeply engaged in this process. Manager involvement was important because managers recognized the work being done by staff, understood the expectations of each job classification, and were familiar with the specific competencies involved in each job classification. They were also called on as subject matter experts throughout the process. There were several training opportunities for these managers as the project moved along, which was key to its success and to staff understanding of the advancement opportunities.

The job classifications that were developed for clinical research staff rely on the idea of competencies being “building blocks.” The staff at a higher tier are expected to have attained their current tier’s expectations as well as the competencies of those at a lower tier. As an example of this for data entry and collection, a “fundamental” employee would be able to collect data according to a predefined plan; an “advanced” employee would not only be able to collect data according to a predefined plan, but is likely to be leading the development of standard operating procedures utilized to collect data.

The tier advancement process is point-based, and is consistent across all tiered job classifications. The institution requires the employee to meet a standardized threshold at each
tier; “fundamental” requiring at least nine points, “skilled” requiring at least 36 points, and “advanced” requiring at least 84 points. Employees can achieve this threshold in many different ways. This allows for growth in areas that will fit staff who have specialties and those who may be a “jack of all trades.” Utilizing the same threshold for all clinical research staff ensures consistency and fairness.

Referring back to Adams’s equity theory of motivation, the tier advancement process provides staff with direct means to see what they are getting out of the job equals what they put in. It also creates a sense of consistency that what they are putting into their job and what they get out is equivalent to that of their peers.

The competency-based tier advancement workforce initiative also meets many of Champagne and McAfee’s aspects of employee needs. It addresses “security,” both in the psychological and economic sense, by providing clear job descriptions and by employing a regular market analysis to ensure fair wages. It speaks to “affiliation” by promoting leadership; in order to advance in tiers, candidates must meet the leadership competencies appropriate for the tier toward which they are working. Leadership and professionalism inherently encourages participation in things outside “the job” that will further the clinical research community. “Esteem” and “self-actualization” are met through the development of challenging job advancement criteria with a definite outcome of achieving the next tier.

Duke will continue to focus on advancing its clinical research workforce. The framework described here is expected to be woven into the institution’s performance review process in the coming years, with the possibility that competency-based assessments will be applied to senior and management positions. By tying these expectations to existing performance and merit review processes, Duke will enhance an already established workflow rather than “reinvent the wheel.”

Conclusion
Shifting the research culture takes time. Standardizing job classifications and introducing new processes for advancement can be of great benefit to staff involved in clinical research.
The role of the clinical research professional needs to be valued, and should be more widely recognized as requiring high-level skills. Advancing the language and expectations in clinical research job classifications allows for a standardized pathway for building a career in an AMC. However, it does not guarantee this by way of tenure, but rather through demonstration of competencies.

By shifting the workforce’s expectations at Duke to competency-based advancement, the institution expects to have less attrition and more job satisfaction among staff choosing to work in clinical research. The tier advancement model has multiple advantages that are anticipated to result in a cultural shift that focuses on advancing clinical research and that leads to improved patient care and health outcomes.

References


**Rebecca Namenek Brouwer, MS,** (rebecca.brouwer@duke.edu) is director of research initiatives at Duke University in Durham, N.C.

**Deborah Hannah, BS,** (deborah.hannah@duke.edu) is research practice manager at Duke University Medical Center.

**Christine Deeter, BS,** (christine.deeter@duke.edu) is operations coordinator at Duke University School of Medicine.

**Betsy Hames, JM,** (betsy.hames@duke.edu) is senior human resources executive at Duke University School of Medicine.

**Denise Clutter Snyder, MS, LDN, RD,** (denise.snyder@duke.edu) is associate dean for clinical research at Duke University School of Medicine.

**Figure 1. Timeline of activities**
Many of us who are now self-employed look back on our 50+ hours a week corporate jobs and wonder how we ever did it—not because we didn’t enjoy our full-time careers, but because our employment is so drastically different now. With the help of recruiters, we build our clientele, choose our projects, and are 100% responsible for our financial growth. Everything we do—and every decision we make—is self-directed. We are the boss.

Four years ago, I switched from my corporate job to the consulting world in order to refocus my priorities and spend more time with family. While sometimes it can be difficult and a bit lonely being the “boss,” at the moment my only employee is me, so I’m fairly motivated to keep this going. That said, there are several important things I’ve learned since becoming my own boss (see Table 1 for some of the resources that helped me along the way).

In the world of clinical research, we LOVE our acronyms. The most appropriate acronym when thinking about self-employment would have to be BOSS (Built on Self Success)

Being your own boss can be a bit scary at first, but going freelance or starting your own consulting business is absolutely worth it if you’re ready to commit. It can be a life in which you live on your own terms, while having the freedom to choose how you spend your time and the projects on which you work. You will get as much out of your work as you are willing to put into it.

**BOSS Essentials**

“To-Do” Lists are a Must
One thing I remind myself of constantly is that procrastination thrives on distraction. I work best with a to-do list, and create one at least once a week; during my busier times, I write out one every day. Without it, I feel unfocused.

Before I started creating a to-do list, I would often get sucked into scrolling through Facebook updates or tidying up the house without realizing how much of my morning had been wasted. To-do lists can be written by hand or maintained in your smartphone.

For her book "To-Do List," author Sasha Cagen surveyed more than 200 people about their list-making habits. She reported that most people (83%) still prefer the tactile experience of writing their lists with pen and paper. The visceral pleasure of crossing things off cannot be underestimated, and people often feel more accountable when a list is in their own handwriting.\[1\] Whatever your preference, create a list.

*Take a Break*

It doesn’t matter when you do it, but on your home office days, schedule a break. No one can be “on” 100% of the time.

I always set a time to take my dogs for a short walk. Not only does it give me time away from the computer, it also gives me time to think about something other than my work. I will put on my headphones, turn on a favorite podcast, and take my pups on a stroll.

Physical movement keeps us from becoming mentally stagnant. We are not designed to sit around all day. As difficult as being sedentary is on our bodies, it’s also no help for our productivity. Getting up for a few minutes to get the blood flowing is a necessary piece of the work day.\[2\]

*Create a Home Office You Want to Work In*

When you work from home, you need to create a functional home office. Feel free to browse Pinterest for inspiration, while keeping in mind that those offices that look amazing may not be set up to accommodate a 40+ hour work week.

In addition to having an area that is functional, it is essential that it is ergonomically fitting. The top of your computer screen should be at eye level or a little below. This way, as you scan down the screen, your eye lids will naturally close a bit and moisten, which reduces eye fatigue.
Position your keyboard so your forearms are parallel to the floor, and adjust your chair so your feet rest firmly on something—the floor or a footrest (if you’re short like me).

Splurge on an office chair that makes you want to put in the hours. If you’re the kind of person who still has paper files, instead of a filing cabinet, try wall storage featuring magazine racks or children’s library–style display shelves. {3}

**Build Your Network**

This is probably the most important piece if you are considering venturing out on your own. Networking is critical to my BOSS career, because no one else is building it for me. While I had a few contacts in the consulting world before I decided to join it, a few contacts won’t get you very far.

Online professional networking with platforms like LinkedIn will help you broaden your circle. You will need to build and enhance your profile, market yourself, and reach out to make those all-important connections.

Also consider adding a ProFinder badge in LinkedIn; this is a service that matches contractors with project managers or recruiters seeking help. Contractors can display a ProFinder badge on their profiles to show prospective clients their skills, expertise, and recommendations. {4}

Your network should include recruiters, others working in your current role, and those working in a role that you aspire to have someday. I take the time to connect with many recruiters, from staffing agency recruiters to human resource contacts at companies that are doing things that I feel passionate about (rare disease, stem cell research, immune-oncology, gene therapy, etc.).

Another great way to connect and grow your network is through professional organizations. ACRP, for example, has multiple opportunities to connect through its local chapters, interest groups, or via its large member directory.

Attending an industry conference that brings together other clinical research professionals is also a great way to connect. Another suggestion is to keep in touch with the great sites you have worked with over the years. Remember those clinical research coordinators (CRCs) and principal investigators (PIs) that you had wished you could “clone”? Stay connected with them. I still keep
in touch with several CRCs with whom I worked 10 or more years ago, because not only did I truly enjoy working with them, but they can also serve as priceless references.

At times, a sponsor company may be looking for someone who is great at creating strong relationships with their sites, or at handling difficult people or situations. A former CRC or PI who can speak specifically about your relationship skills could be very valuable. This in turn could bring you the additional business you are in search of.

Lastly, never burn bridges. While it may be tempting to tell your boss off in some dramatic fashion, aim for a professional and graceful exit. Your former coworkers and employer could be some of your best advocates down the road.

Financial Considerations

As a consultant, it is very important to keep tabs on your financial wellness. You will be responsible for taking taxes out of your income, so always set aside 30% of whatever you make—just lock it up in a separate savings account, if that helps.

Many of the consultants I know are comfortable with using QuickBooks Self-Employed, but I personally work with a local CPA in my area, and pay my taxes on a quarterly basis. Another thing you will no longer have as a consultant is a 401(k), so I recommend setting up a IRA and depositing regular amounts into it every month.

Remember that expensive laptop your previous employer provided when you started working there? The monthly allowance you had for cell phone and internet charges? As a self-employed consultant, you have to pay for everything you decide you need—it comes out of your pocket, not someone else’s budget.

As a fulltime employee of a contract research organization, study site, or pharmaceutical company, you probably have a nice benefits package. As a consultant, unless you are married and can be added to your spouse’s benefits, the monthly cost of basic health insurance can be as high as $800 for an individual in good health.

Another thing to keep in mind is your plan for vacation savings. As a consultant, there is no paid vacation time. Because income as a consultant can be variable, I have always paid myself a set
income each week, and anything extra goes into a savings account. That savings account is where I maintain extra funds that will go toward vacations or other luxuries.

Make a Work Schedule

Imagine what your work day might look like if there was no routine—no rules, nothing expected of you, no set hours. I know what you’re thinking—“Whoo-hoo!”—but in reality, it would be completely chaotic. Nothing would ever get done, people would be upset, and things would fall apart.

I have adopted a fairly set work schedule with log-on and log-off times. As a consultant, you are responsible for setting and sticking to your working hours. I used to start the day at varying times, but failing to establish my hours and getting caught up on work in the evenings had a negative impact on my personal relationships.

A day without a plan can sort of end up going nowhere. Sticking to your schedule means getting things done; it’s an outline for the day, and all you need to do is follow it.

Lessons Learned from Being Your Own Boss

You Will Face Challenges That You May Not Have Expected

If you are like me—someone who went from full-time employment with a mid-sized organization to working with mostly tiny pharmaceutical or biotech companies—then you will probably be able to relate to this section. Many small companies have an incredible compound that they want to develop, but they lack the infrastructure to support everyone working toward this shared goal. They don’t have information technology departments to help you if their home grown, virtual desktop electronic data capture system won’t load on your business laptop. They may not have the kinds of standard operating procedures you are used to, or are creating them as they go.

Such companies will often lack even the most essential forms and templates you would expect in a clinical research environment. Initially, this felt very odd for me; I craved the structure and “rules” that I had while working with larger companies. While there are times when I still desire
that structure, I have found that sharing my past experiences can help the sponsor put some structure in place.

I have enjoyed creating my own tools and templates to do my job, and appreciate the support and freedom to do it. While rules can be very valuable, it has also been refreshing to be able to “think outside the box” as a consultant supporting a small company.

*You Get to Do Work That You Enjoy*

Richard Branson reminds us that “some 80% of your life is spent working.”{5} As a consultant, you get to decide what projects you accept. Find yourself a “niche” area—something you are passionate about. For me, this has been projects in oncology and rare diseases; I find them challenging and interesting, but my desire to contribute to those suffering or who have family members suffering with cancer or a rare disease also pushes me along and keeps me inspired.

Ultimately, work-life happiness comes from doing meaningful things. We all want to work for a worthy purpose or cause and know that our work is actually making a difference. Working for yourself will allow you to define what's meaningful to you.

*You Know More Than You Think*

Believing in yourself and your vision of success is also one of the most important steps in the entire process of going solo. Part of believing in yourself means recognizing that you have everything it takes to plant the seed of self-employment. Don't get hung up on all the stuff you don't know.

Working toward a professional certification in clinical research is one piece that will help assure your potential clients that you are committed to and competent in the field. Once you have done that, focus on making your dream a reality by doing everything with what you DO know.

*You Actually HAVE a Boss*

You may technically be your own boss, but not really. Your clients are truly your boss—they rely on you, and you rely on them. In this industry, the health of your business is your boss, and that health is driven by continued work. You can’t miss commitments and still be successful. Your word is your most powerful asset.
Before Starting, Have a Purpose

*Have Clarity on Your “Why”*

Your “why” will be the gravity that keeps you grounded when you want to quit. When you first begin your journey, you will want to have a clear picture of where you are going and WHY you want to get there. Your WHY is what motivates you.

For me, my primary WHY was my family. In my former job situation, I returned to work (and travel) when my daughter was five weeks old and when my son was 10 weeks old. Each time, it was heart wrenching; there were many “firsts” in their lives that I missed. While I cannot turn back time, when things got really rough in 2013, I knew that I could change my current circumstances by going solo.

*Make a Vision Board*

At the risk of sounding like a New Age guru, making a vision board works. Spread out the design of your ideal life in pictures and notes and objects on a big board, and be specific.

- What do you want to accomplish by being self-employed?
- How much money do you want to make?
- Do you want to buy a new house or car?
- What vacations will you take?
- Why is this important?

Whatever the answers are, place them on the vision board. You will want to keep your goals in front of you at all times. I have my vision board beside my computer monitor in my home office. It has photos of places I want to visit with my family, goals I want to accomplish, and phrases that remind me of my “why,” such as “attain harmony,” “learn and travel,” “walk your truth,” and “focus on now.”
Final Thoughts

There's a story described in Napoleon Hill's book "Think and Grow Rich" that tells you how it is to be the captain of your own ship, the BOSS. It represents one of the main resources you’ll need on your path to achievement—a burning desire to succeed.

A long while ago, a great warrior faced a situation which made it necessary for him to make a decision which insured his success on the battlefield. He was about to send his armies against a powerful foe, whose men outnumbered his own. He loaded his soldiers into boats, sailed to the enemy's country, unloaded soldiers and equipment, then gave the order to burn the ships that had carried them. Addressing his men before the first battle, he said, "You see the boats going up in smoke. That means that we cannot leave these shores alive unless we win! We now have no choice—we win—or we perish!" They won.

Being a full-time employee of an established company is like going to battle, but not burning your ships before the battle. You remind yourself that you have something secure, and although you may wish to achieve more than what can be accomplished at that company, you keep coming back to that idea of stability and security. There is peace of mind knowing how much money you will make at the end of the month. Although this desire for stability is understandable, often this route will also crush your dreams. That being said, not everyone is built to be self-employed.

Consulting can offer you incredible experiences, but it also asks for a significant investment of your time and energy along with the willingness to accept potential instability. A key point to keep in mind when you are an independent consultant is that flexibility is not only a requirement for yoga. Consulting can be a great way to gain experience with different sponsor companies, but it also means that you have to constantly adapt and be as flexible as possible with your time and work style in order to meet their needs.

Remember to dust off your “elevator pitch,” because consulting calls for the art of making connections—not only in terms of the work, but perhaps more importantly, with people. Developing solid networks, is crucial. So, if you feel that you can be a team player (even if you
are not “technically” part of the employee team), if you are willing to work hard on building and fostering relationships, if you have or are willing to work hard on self-discipline, and if you know your “why,” then maybe it’s time to give consulting a try.

Table 1: Resources for Becoming Self-Employed

<table>
<thead>
<tr>
<th>Title</th>
<th>Website/Author</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Start Your Own Business</em></td>
<td><a href="https://www.usa.gov/start-business">https://www.usa.gov/start-business</a></td>
</tr>
<tr>
<td><em>7 Steps to Becoming Self-Employed</em></td>
<td><a href="https://www.theselfemployed.com/start_ups/7-steps-to-becoming-self-employed/">https://www.theselfemployed.com/start_ups/7-steps-to-becoming-self-employed/</a></td>
</tr>
</tbody>
</table>
| *Go Independent: The Essential Guide to Becoming an Independent Consultant and Maximising Your Relationship with Your Client* | Nigel James Hunt  

References

www.huffingtonpost.com/kate-bartolotta/5-science-backed-ways-taking-a-break-boosts-our-productivity_b_8548292.html

5. Soos I. 2015. A 6-sentence story perfectly sums up what it's like to be your own boss. 


Nicole Tesar (ntesar@harmonyclinicalconsulting.com) is owner and director of clinical operations with Harmony Clinical Consulting Corporation in Avon, Ohio.
Clinical Research Nurse Career Advancement Using Clinical Ladder Programs

LEARNING OBJECTIVE
After reading this article, participants should be able to understand clinical ladder programs and articulate how they can be used to enhance the career of a clinical research nurse.

DISCLOSURE
Paula Smailes, MSN, RN, CCRC, CCRP; Holly Bookless, BSN, RN-BC; Carrie Blumenauer, BSN, RN: Nothing to disclose

1. What was the major turning point for clinical research nurses in August 2016?
   A. The International Association of Clinical Research Nurses (IACRN) was formed.
   B. The American Nurses Credentialing Center established a recognition program.
   C. Clinical research nurses were recognized for their role in ensuring subject safety.
   D. The American Nurses Association (ANA) formally recognized clinical research nursing as a part of the profession.

2. The IACRN and ANA joined forces to develop standards which enable nurses to gain skills in clinical research. How will these skills be utilized in clinical research?
   A. To define and validate clinical research best practices across all studies.
   B. To ensure and maintain clinical quality compliance across the organization.
   C. To provide safe, accurate, efficient, and ethical care that complies with regulations.
   D. To support the professional development of nurses and contribute to research nursing as a speciality.

3. Clinical ladder programs center around stages of development for nurses. What are these stages?
   A. Novice, advanced beginner, competent, proficient, expert
   B. Trainee, beginner, intermediate, advanced, expert
   C. Basic, fundamental, intermediate, advanced, proficient
   D. Beginner, skilled, competent, advanced, leadership, expert

4. The recognition program put together by the American Nurses Credentialing Center is regarded as which of the following?
   A. One of the highest levels of nursing standards.
   B. The leading standard of best practices in nursing.
   C. The highest level of safety, quality, and patient satisfaction.
   D. One of the international gold standards for quality in healthcare.
5. What are the components of the Magnet Model that organizations must meet?
A. Transformational leadership, structural empowerment, exemplary professional practice, new knowledge, and empirical quality results.
B. Leadership and professionalism, quality patient care, innovation and improvements, and research-driven results.
C. Scientific concepts and research design, ethical and participant safety considerations, medicines development and regulation, and communication and teamwork.
D. Attributable, legible, contemporaneous, original, and accurate.

6. What are the clinical research nurse responsibilities in a research center?
A. To uphold the principles of ICH GCP, adhere to the organization’s SOPs, ensure quality care delivery, and correct storage of samples collected.
B. To be prepared to encounter many different populations with a variety of conditions, including rare diseases and first-in-human agents.
C. To move research protocols from concept to reality while at the bedside, while ensuring safe and accurate encounters for each participant.
D. To ensure that they meet the defined criteria of clinical excellence, skills and competence, professional expertise, and educational attainment.

7. What are the primary reasons for using ladder programs in an organization?
A. To establish training needs and career advancement.
B. To bolster staff retention, productivity, and job satisfaction.
C. To ensure compliance to organizational SOPs and improve quality.
D. To offer a system of stages that employees need to work in to gain experience.

8. How do nurses who are active in clinical ladder programs contribute to their centers?
A. By actively engaging in quality improvement, participant safety and satisfaction, and staff engagement.
B. By enhancing research participants’ experience at the bedside and ensuring their safety at all times.
C. By providing support to other nurses within the organization and ensure basic practices are followed.
D. By setting a standard of care that results in positive satisfaction scores and healthy outcomes.

9. What is the most significant reason that a clinical research nurse should participate in a clinical ladder program for career advancement?
A. To provide patient care and contribute to improving quality research at the center.
B. To be at the core of cutting-edge clinical research and healthcare outcomes.
C. To seize the opportunity to advance their skills and career while being able to stay at the bedside.
D. To attain clinical research certification and stay current with best practices.
10. **Clinical ladder programs have delivered proven impacts for the main stakeholders. Who are they?**
   A. Patients, employers, and nurses.
   B. The pharmaceutical industry, investigators, and clinic managers.
   C. The American Nurses Credentialing Center and the Magnet Recognition Program.
   D. Regulators and the International Association of Clinical Research Nurses.

**Recruit, Train, and Retain the Best: The Implementation of a Competency-Based Clinical Research Workforce Initiative**

**LEARNING OBJECTIVE**
After reading this article, participants should be able to understand the process of standardizing job classifications and identifying a pathway for building a career in an academic medical center.

**DISCLOSURE**
Rebecca Namenek Brouwer, MS; Deborah Hannah, BS; Christine Deeter, BS; Betsy Hames, JM; Denise Clutter Snyder, MS, LDN, RD: *Nothing to disclose*

11. **As described in the article, what was the intent of the competency-based staffing initiative at an academic medical center?**
   A. To motivate staff by helping them identify that what they put into the job relates to what they get out of it.
   B. To address the challenges academic medical centers face when hiring skilled and trained clinical research staff.
   C. To develop a process that has the necessary elements and can fit in with the institutions’ current performance review process.
   D. To provide standardized research roles, a consistent approach to hiring, a transparent career pathway, and advancement opportunities based on noted competencies.

12. **Which of the following is one of the aspects of Champagne and McAfee’s motivational theory?**
   A. Social
   B. Affiliation
   C. Economic
   D. Psychological

13. **How many competency domains were developed by the Joint Task Force for Clinical Trials Competency?**
   A. Eight
   B. Twelve
   C. Four
   D. Nine
14. The CRPWG was tasked with consolidating the number of clinical research job classifications. What did this result in?
A. Job classifications were simplified and easier to understand.
B. Job classifications were reduced from approximately 80 to 12.
C. It provided consistency and standardization of job classifications across the institution.
D. Four levels of competency were identified: fundamental, skilled, leadership, and professionalism.

15. More than 40 competencies were identified for tiered positions. How many categories were these levelled into?
A. Three
B. Eight
C. Four
D. Twelve

16. What effect does utilizing the tools developed for the tier advancement process have on hiring new employees?
A. It creates consistency and efficiency across various therapeutic areas.
B. It allows individuals to identify a career path in their new role.
C. It provides information on a new employee’s capabilities.
D. It has no effect on the hiring of new employees.

17. Completion of a competency assessment provides an individualized profile that can be part of an employee’s portfolio. How does this assist the employee should he or she need to relocate to another city?
A. The portfolio forms part of the career path in the tier-based process.
B. The portfolio allows another employer to gauge possible roles that will be a good fit for the individual.
C. Other academic medical centers do not need to interview the employee since they can review the portfolio.
D. Portfolios provide information on staff capabilities to other academic medical centers so an employee can continue working at the same level.

18. How did managers’ involvement play an important role in the project?
A. Managers were provided with several training opportunities.
B. Managers were able to serve on the Faculty Advisory Committee.
C. Manager involvement allowed for different disciplines to be evaluated and encouraged diversity.
D. Managers recognized the work being done, were familiar with the specific competencies, and understood each job classification.
19. Employees are required to have a certain number of points at each tier. The least number of points required for “fundamental,” “skilled,” and “advanced” tiers, respectively, are which of the following?
A. 9, 36, 84
B. 5, 9, 36
C. 5, 8, 12
D. 9, 12, 36

20. What are the expectations of the institution when shifting to a competency-based advancement of workforce?
A. Clearly defined roles and responsibilities for individuals working in clinical research.
B. More job satisfaction and less attrition among staff in clinical research.
C. Recognition of competencies achieved and identifying skills required for further development.
D. Identification of potential candidates for future senior and management positions within the clinical research department.

The Clinical Research BOSS: Built on Self Success

LEARNING OBJECTIVE
After reading this article, participants should be able to describe the proper design, utilization, and benefits for self-employment of “to-do” lists, home offices, networking tactics, financial planning, and scheduling.

DISCLOSURE
Nicole Tesar: Nothing to disclose

21. The use of to-do lists by self-employed persons helps to avoid which of the following?
A. Losing records demanded by regulatory authorities.
B. Forgetting to follow up on unpaid invoices to clients.
C. Simultaneously working for companies that compete with one another.
D. Procrastinating on work due to distraction.

22. According to a survey referred to in the article, most people prefer to make to-do lists in which format?
A. Voice memos on smartphones
B. Hand written with pen and paper
C. Calendar reminders in e-mail programs
D. Automated text messages
23. A key reason noted for “taking a break” from desk work from time to time is based on which of the following?
   A. Movement prevents problems with concentration and productivity.
   B. Most work-at-home individuals suffer from heart conditions.
   C. IRS auditors are suspicious of consultants who report eight-hour workdays.
   D. Most work-at-home individuals earn flat fees rather than hourly wages.

24. The article suggests all of the following options for job-related networking except which one?
   A. Using online platforms.
   B. Joining professional organizations.
   C. Participating in alumni reunions.
   D. Attending industry conferences.

25. Your professional network should include which of the following groupings?
   A. Recruiters, people in job roles like your own, people in job roles you wish to attain
   B. Regulators, people in job roles you are overqualified for, people who earn more than you
   C. Executives, assistants to managers in roles you desire, vendors for companies you admire
   D. Ex-employees of companies you admire, consultants you compete with, industry analysts

26. According to the article, how much of your income should you set aside for financial safety?
   A. 15%
   B. 20%
   C. 25%
   D. 30%

27. Setting your work schedule as a routine is a good practice for which of the following reasons?
   A. Regulators expect work-at-home individuals to keep regular hours.
   B. An unplanned day can be unproductive.
   C. Unpredictability in scheduling can lead to sleep disorders.
   D. Accountants at client firms will demand it before processing invoices.

28. To do work you enjoy, the article suggests which of the following tactics?
   A. Work on constantly different projects outside your area of expertise.
   B. Work for clients who will demand your exclusive services.
   C. Work in a specialized area that you care about greatly.
   D. Work on projects with tight deadlines so you must stay busy.

29. Which of the following demonstrates your commitment to and competency in your work?
   A. Always submitting precise “request for proposal” details.
   B. Never charging clients for work supplies or necessary resources.
   C. Being professional and timely with correspondence to clients.
   D. Making efforts to achieve certification in clinical research.

30. According to the article, a vision board can be useful for which of the following purposes?
   A. Improving your communication skills.
   B. Making you pay attention to your goals.
   C. Keeping track of your work expenses.
   D. Reminding yourself to take breaks.