International Journal of Clinical Trials
Paglione ML. Int J Clin Trials. 2024 May;11(2):156-161
http://www.ijclinicaltrials.com
pISSN 2349-3240 | eISSN 2349-3259
DOI: https://dx.doi.org/10.18203/2349-3259.ijct20240967

Review Article

A day in the life of a clinical research nurse

Melanie L. Paglione*

Department of Obstetrics and Gynaecology, The Ohio State University, Columbus, Ohio, United States

Received: 11 November 2023
Revised: 08 January 2024
Accepted: 01 March 2024

***Correspondence:**
Melanie L. Paglione,
E-mail: melanie.paglione@osumc.edu

ABSTRACT

Have you ever wondered, what does a clinical research nurse (CRNs) do from day-to-day or week-to-week? This article will attempt to answer those questions by including what defines research, clinical research and a CRN. Topics will also include the roles in which CRNs are responsible for or can complete, the challenges they face and their importance in clinical trials. In additional, advantages of being a CRN will be reviewed and how this can powerfully change your view on the career and then stories from CRNs at two major academic research institutes will be reported and how lives are changed because of research nurses. If you read this article and determine that this path may be what you want to pursue or learn more about, the writer has included a section about training and certification which can be reviewed and explored. Also included is knowledge which is helpful to learn when exploring this topic.

Keywords: Clinical research nurse, Responsibilities, Challenges, Advantages

INTRODUCTION

Whether you call it clinical research nurse (CRN), clinical research specialist, clinical trial coordinator, research nurse coordinator, etc. the roles, responsibilities and names are very similar.[1] Depending on the institution or company that the nurse is employed by, job titles may vary and are subject to human resource job title adoptions. Regardless of job title, CRNs serve as a key clinical staff member on clinical trials. According to the American Association of Colleges of Nursing, nurses account for the highest percent of healthcare professionals in the United States amounting to 4.2 million registered nurses nationwide.[2] Of those nurses, about 1.9 million are employed in some sort of research position whether that be in an academic institution, private company or federal agency.[3] The CRN title was recognized by the American Nurses Association (ANA) in 2016 as a specialty practice in nursing.[4] This recognition provided an important milestone for CRNs who had been working in clinical research for decades.

So, what is clinical research? This is any formal or informal research project or clinical trial which include humans as participates and may include an investigational product (biologic, device, drug) or treatment activity. All clinical trials are reviewed and approved by an Institutional Review Board (IRB) and will have several requirements that need to be followed specifically in order to provide safe and ethical care for the participants and performance of the study.

TRAINING

Any registered nurse as long as they are licensed can be a CRN, whether with a master degree, bachelor degree, diploma, or associate degree. Most institutions prefer the baccalaureate degree or higher, especially if they are credentialed through agencies such as The Joint Commission. The learning of the research portion comes through on-the-job training and computer-based learning modules (CBLs). The basic trainings will include good clinical practice, general/research HIPPA requirements, human subject protections including ethical considerations

and responsible conduct in research. Several academic institutions will provide access to online training certificate programs such as CITI (Human Subject Protection, Good Clinical Practice Guidelines, Responsible Conduct of Research and Clinical Research Coordinator Training). Additional training requirements may be needed depending on the type of research and complexity that the nurse will be participating in or the roles they will be responsible for. In addition to the CBLs, the nurse will be required to read and understand the protocols and manuals of operations and procedures (MOP) as well as the standard operating procedures (SOP) for the department/company/organization they are employed by and be able to prove their basic knowledge of those items. There may additionally be training and quizzes required for the specific trial the CRN is working on. For instance, the Maternal Fetal Network Units Network (MFMU) has 1-6 quizzes and in person checkoffs forms which must be submitted to them and passed prior to the employee performing any portion of the study with human participants. In addition, most research organizations encourage their member to get certified in research. Two common agencies who offer these certificates in the United States through exam are the Society of Clinical Research Association (SoCRA) or the Association of Clinical Research Professionals (ACRP).[5] Additionally, the International Association of Clinical Research Nurses offers a certificate program through a portfolio called the CRN-BC certification.

ROLES AND RESPONSIBILITIES

The role of the CRN can be a quite complex range of activities (Table 1). Depending on the study will depend on the role but generally speaking a CRN can perform a portion or a majority of the trial activities. After thorough review of the protocol and MOP the CRN can screen potential patients to see if they are eligible for the studies, consent the participant, randomize them (if a part of the study) and then complete the initial study visit. Parts of these visit can include collecting medical histories including current symptoms and medication use as well as collecting baseline vital signs. Most trials also include specimen collection throughout the study timeframe including but not limited to blood, urine, spit, stool, bacterial or viral swabs of different areas such as nasopharyngeal or nasal, etc. The nurse can be responsible for scheduling the visits according to the protocol and then completing the visits. They can also administer study drugs to the participants including orally, inhalation, intravenous, intramuscular or subcutaneous as well as then monitor for any adverse effects of the administration. As a part of the CRNs role, providing oversight of the participant's care is imperative which involves making sure the rest of the research team is abiding by the protocol and advocating for the participant and their care.[6] As a nurse, the job of educating the participant is still a part of the role. Educating the participant on the study visit schedule, expectations, disease/condition management, and treatment is very helpful in supporting the participant as well as educating the families, if involved. Inclusion of families is very critical to help the participant feel supported and cared for.[7] As far as data collection and management is concerned the CRN can be responsible for the collection of health information from the participant and electronic/paper medical records and then entering it onto paper clinical research forms (CRFs) or electronic clinical research forms (eCRFs). Consistency on completion of this task is imperative and requires training of data collection. Regulatory items can also be managed by a CRN, these include working with the Investigational Review Board (IRB) on the trials, making sure that the SOPs are up to date and complete, working with the sponsor or institutions as well as making sure training is completed properly and documented accurately. According to the American Nurses Association (ANA) and the International Association of Clinical Research Nurses (IACRN) they noted 5 different domains in which CRNs work in and include "Human Subjects Protection; Care Coordination and Continuity; Contribution to Science in General and Nursing Science/Practice; Clinical Practice; and Study Management."[4] (Figure 1) Other roles in which CRNs can be trained and take part in is starting up new studies, funding and financial aspects of clinical trials, writing proposals, and result interpretation with the help of statisticians.[8]

Table 1: CRN role activities.

S. no.	Activities
1	Study feasibility assessments
2	Protocol and case report form development
3	Study project management
4	Staff supervision and management
5	Recruitment
6	Informed consent
7	Medical product administration and accountability
8	Data collection
9	Data management
10	Regulatory submissions and tracking
11	Quality improvement
12	Business management
13	Patient care

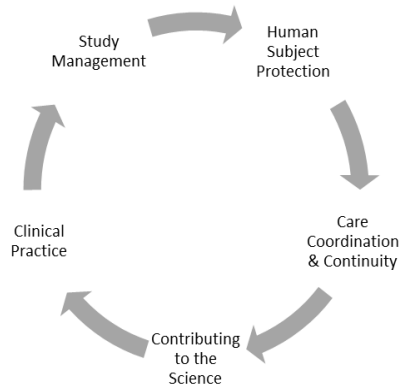

Figure 1: CRN domain of practice.

CHALLENGES OF BEING A CRN

As a CRN there are some common challenges that are faced. Some of the most common challenges are staying in the role of a "research professional", feeling isolated, as well as salary differences between a clinical research member and clinical staff member. As a research nurse the role of caring for the participant is different than caring for a patient in the clinical setting. For example, in blinded studies, the CRN is not able to tell the participant which drug is being given (if it is known), and must make sure to follow the protocol exactly. In the clinical setting the physician is in charge of the patients care and can make any decision for their care but in research the PI or co PI must stick to the protocol. An example of this, is that participants have a specific time frame they are supposed to be seen and if not seen in that time it could be considered a protocol violation and affect the results and validity of the study. Knowing the rules and regulations is necessary for accurate and correct study activities and results.

Isolation is another common disadvantage in the transition to becoming a CRN. A study published in 2007 which looked at a focused group of 9 CRNs noted that they "experienced isolation and felt that they were perceived as a minority group of "nurse-researchers" as opposed to nurses working on 'medically led' research".[9] The relationship between the CRN and clinical research nurses is essential and if good, will be seen by evidence of good patient care and successful clinical trials.[1] Lack of clinical research education and role progression pathways has been identified as a gap.[10] Lastly, salary differences between research nurses and clinical nurses can be significant. Upon interviewing an associate director of a research department, she claimed that unfortunately, clinical research nurses start out getting paid less salaries than clinical nurses working in the hospital or clinic. She stated that even though they were doing basically the same job, the difference in salary was significant. (K, Carter, personal communication, September 29, 2022) At another institution, research nurses are not a part of the nursing union and therefore salary is different. This makes it difficult for nurses to move from a position of clinical to research unless they are able to negotiate their rate or move at the right time. After a quick google search at one of the largest academic research institutions in Central Ohio, the average salary for research nurses in 2021 was $62,143 per year verse a registered nurse being $76,185 per year.[11] After interviewing a nurse who is a Clinical Research Manager at The Ohio State University, she stated that they have had several mid to late career clinical nurses apply for CRN positions only to find out their salary would decrease if they switched and so the positions were declined by the individuals (A. Bartholomew, personal communication, October 19, 2022).

ADVANTAGES OF BEING A CRN

Apart from challenges there are so much more advantages for being a CRN. These include closer relationships to participates, the opportunity to be a part of life changing research, closer ability to determine abnormalities and get care, better work/life balance, better work schedules, not having the stress of being a bedside nurse and working in an environment which changes often. A qualitative study of CRNs revealed role themes included dual fidelity to the protocol and study participants; interdisciplinary team membership and contributing to the science.[10] The desire to help others and have a trusted relationship with people are some of the top two reasons nurses become nurses. By being a part of research, you are not only potentially helping others feel better and get better, you are a part of the cutting-edge research studies that could potentially help not just one or two people but hundreds to millions in the future.[12] Having this opportunity to see innovative ideals, devices, medications and knowledge is empowering and rewarding. In addition, most research studies require the participants to attend multiple study visit appointments allowing for the CRN to develop deeper relationship and the ability to detect AEs (adverse event) quicker and more often which relates to better care and a bigger sense of bonding, self- value, or worth. Having this relationship can then also impower the nurse to be a better advocate and care taker of the participants. In the event of an AE or SAE (serious adverse event), the CRN must talk with the PI and determine the best course of action which may include additional services including PT, OT, or other therapies, medications or testing.

Research typically occurs during normal business hours on weekdays. With this timing, it allows CRNs and other staff to work during the day and then be home in time for dinner and children's sports which happen on the weekday. Researchers are typically off on the weekends and have a consistent schedule, allowing for time to plan events and spend more time with family and friends. This allows for a better work-life balance which includes less stress for the CRN and more happiness overall. Lastly, the role of a CRN is ever changing, which provides excitement and interest.[12] The basics, rules and regulations stay the same but there are studies in different stages from starting and recruiting, to data collections, site visits, closing studies and data checks. With these changes there is also an opportunity to learn continuously within the role.

REAL LIFE STORIES FROM CLINICAL RESEARCH NURSES

In the fall of 2022, several CRNs were interviewed and their stories and experiences were captured below, which provides illustrations of the CRN domain of practice.

Story from a labor and delivery study CRN (clinical care; human subject protection, study management)

A new local study was looking at different doses of an FDA approved injectable pain medication to see if a higher dose would help decrease overall pain in patients undergoing cesarean delivery. She noticed shortly after starting that participants were receiving a dose that was 30 mg more post-partum (significant amount) than they should have been getting in a full 24 hr period. The PI was

able to make a protocol amendment and send it to the IRB for approval to make it safer for participants (D. Doan Mast, personal communication, September 22, 2022).

Story from a rare disease study coordinator with was working with a CRN (care continuity and coordination, clinical care)

The study coordinator was working with a CRN colleague who was working with a study participant in a rare disease study. When checking vital signs, she noted that the blood pressure was very high, in fact too high to send home without treatment. The CRN talked with the participant and asked more questions and triaged them realizing that the participants were homeless and ran out of their blood pressure medications and then couldn't afford to get more. They were able to get social work involved to help with the medication and a family member to help with housing. The CRN intervention was life-saving (K. Carter, personal communication, September 29, 2022).

Story from a wound care study CRN (clinical practice; contributing to the science, study management)

According to the protocol of the current study, they wanted the method of collection of fluid to be collected in a certain way from the wound suctioning device. From her experience and knowledge, she knew that there had to be a better, more efficient and easier way for the staff and participant. Therefore, she went to the leadership and sponsor and presented her thoughts and ideas. They were able to be more successful in the study which led to better results for the study and participant potentially. Without her innovative idea and knowledge, the study could have been less successful (D. McGowan, personal communication, October 24, 2022).

Story from a diabetes study CRN (care continuity and coordination; clinical care)

During a study visit that required a Hemoglobin A1C (HgbA1C) (diabetes test) in the clinic via finger stick, the testing device did not report a value. The CRN decided to repeat the test with the same null result. Then the CRN investigated why the machine would not read results and discovered in the user manual that if the participant's hemoglobin (blood volume) was too low it would not read. The CRN conferred with the principal investigator and obtained a stat CBC (complete blood count) order, which revealed that the participant had a critically low hemoglobin and needed a blood transfusion, which was able to be completed the same day. If the nurse was not a part of the team and responsible for this collection of specimens then other staff may have just requested a blood draw HgbA1C and would have never found out the participant was very anemic. Because of the CRNs triaging knowledge, critical problem-solving skills and taking the next steps the CRN was able to investigate and learn more (H. Bookless, personal communication, October 24, 2022).

Nurses have the knowledge and natural ability to anticipate side effects and worse case scenarios preparing them better for research. They are able to probe for questions from the participants and get to the bottom of issues whether study related or not. They can have all the necessary medications prepared in case of crisis medically and be ready to respond quickly. One CRN stated, "nurses are professional worriers" further explaining that this trait allows them to be ready to triage and assess any situation quickly. She stated that the lessons learned in the career of a nurse are invaluable to research and the need for nurses on research are also invaluable (H. Bookless, personal communication, October 24, 2022).

Story from adult chronic disease CRN (clinical care; continuity of care, human subject protection)

Two specific cases were reported. First, she was completing the initial visit with a participant and learned that they were not taking their medications the ways they were written, which was causing their chronic health conditions to not be controlled. She was able to notify their primary doctor and teach the participants the best way to take the medications to help them feel better. She stated that this happens often, either participants do not understand the directions, they cannot afford the medication as often so they decrease the amount to take or they don't understand the reasoning for the way it is prescribed. As a nurse, she is able to educate the participants and help them understand the reasoning or get them help with getting their medications more regularly. She was also a part of a new research study that required negative COVID testing prior to admission to the hospital for a study drug infusion. The protocol wanted to have the participants transported to the hospital via taxi one day prior to have the testing completed in the car (drive up testing) and then would report the next day to the facility. She and her team thought that this would increase the risk of exposure for the taxi drivers and was able to get the protocol changed to being admitted to the hospital one day prior to have the testing completed along with baseline labs therefore decreasing exposure to additional non-medical persons (K. Neidert, personal communication, October 24, 2022).

Story from a cardiology study CRN (continuity of care, clinical care, human subject protection)

"I was conducting a follow-up visit with one of our study participants (early 40s, post-MI arrhythmia clinical trial). I noticed when he walked up the hall that his arms seemed to be stuck by his sides, in other words, his arms were not swinging at all. During the visit, in addition to collecting labs and conducting an EKG, I was also assessing him for adverse events. I asked him to walk for me again, paying attention to his arm movements. I asked him to raise his arms up, but he could not and he also broke down crying. With probing, I realized his shoulders had become frozen because after his heart attack and angioplasty, he was sitting in the recliner, watching TV all-day and afraid to

move about, in case he had another heart attack. He also talked about his depression after his MI. Depression is a known side effect after open-heart surgery and angioplasty. I worked with the PI to get him a referral to orthopedics to un-freeze his shoulders, and to cardiac rehabilitation. We also got him a prescription for an anti-depressant. This is a great example of the value of nursing assessment during a study visit" (C. Jones, personal communication, November 3, 2022).

DISCUSSION

After review of research associations data and several journal articles we can see that this role is complex and highly valuable but only sought after by a handful of nurses.

Figure 2: Clinical research team: The Ohio state University Medical Center, Department of Obstetrics and Gynecology, Division of Maternal Fetal Medicine
Pictured from left to right- Kayla McDaniel, CRC, BS; Cindy Overholts, Senior CRC, BA, CCRC; Melanie Paglione; CRN, MCR, BSN; Taryn Summerfield, MS, BS, CCRP and Devra Doan Mast, CRN, BSN (verbal authorization given for publication, per institution guidelines – written authorization not needed).

CONCLUSION

As evidence from the above exemplars, the need for CRNs is critical to the execution of clinical research studies and having one on the team is necessary to the results of a clinical research studies. Their training and assessment skills enable them to probe a little more, critically think and question. CRNs are natural patient advocates and also advocate for the research. This is invaluable to the care of participants and value of research.

ACKNOWLEDGEMENTS

Special acknowledgement to Holly Bookless, Karen Carter, Carolynn Jones, Devra Doan Mast, Dina McGowan and Kelly Neidert for sharing insight and CRN stories as well as Vince Iwuji for his peer review and dedication to nursing. Author would also like to thank all the professors at The Ohio State University MCR program for helping me accomplish my goal of a Master Degree.

Funding: No funding sources
Conflict of interest: None declared
Ethical approval: Not required

REFERENCES

1. Hernon O, Dalton R, Dowling M. Clinical research nurses' expectations and realities of their role: A qualitative evidence synthesis. Journal of Clinical Nursing. 2019;29(5-6):667-83.
2. American Association of Colleges of Nursing. Nursing Fact Sheet; 2022. Available at: https://www.aacnnursing.org/news-Information/fact-sheets/nursing-fact-sheet. Accessed 26 October 2023.
3. U.S. Bureau of Labor Statistics; 2022, October 20. U.S. Bureau of Labor Statistics. Available at: https://www.bls.gov/. Accessed on 21st October 2022.
4. American Nurses Association and International Association of Clinical Research Nurses. Clinical research nursing: scope and standards of practice. Nursesbooks; 2016.
5. Mackey A, Bollinger M, Lynch, S. Nursing for women's health. Clin Res Nurs, 2012;16(4):325-9.
6. Smith H, Wilson J McInerney V, Kelsey M, Foley J, Clarke MM. 2017/2017 Irish Research Nurses Network Survey on Research Nurses/Midwives in Ireland (Initial Report). Irish Research Nurses Network. Available at: https://irnm.ie/wp-content/uploads/2018/03/Initial-Report-from-the-2017-2018-Irish-Research-Nurses-Network-Survey-on-Research-Nurses-Midwives.pdf. Accessed 26 October 2023.
7. Hastings CE, Fisher CA, McCabe MA. Clinical research nursing; A critical resource in the national research enterprise. Nursing Outlook. 2012;60(3):149-156.e143.
8. Stephens-Lloyd, A. The extended role of the clinical research nurse: Building an evidence base for practice. NT Res. 2004;9(1):18-27.
9. Spilsbury K, Petherick E, Cullum N, Nelson A, Nixon J, Mason S. The role and potential contribution of clinical research nurses in clinical trials. J Clin Nurs. 2007;17(4):549-57.
10. Jones CT, Griffity CA, Fisher CA, Grinke KA, Keller R, Lee H, et al. Nurses in clinical trials: Perceptions of impact on the research enterprise. J Res Nurs. 2022;27(1-2):50-65.

11. Job search, indeed. (n.d.). Available at: https://www.indeed.com/. Accessed on 21st October 2022.
12. Hyland D, Clarke MM. Spotlight on clinical research nursing. Focus. 2016;24(3):52-3.
13. Poston RD, Buescher CR. The Essential Role of the Clinical Research Nurse (CRN). Urologic Nursing. 2010;30(1):55-77.

Cite this article as: Paglione ML. A day in the life of a clinical research nurse. Int J Clin Trials 2024;11(2):156-61.