**0024**

**Clinical Research Nurse Certification Council (CRNCC)**

* 1. **Professional Growth:**
  2. I am a first-generation college graduate and the first in my family to engage in public speaking and writing. Publishing and presenting nationally and internationally was never a consideration for me until I began my journey in clinical research. While it may seem second nature to present at the podium and educate others publically, the act sometimes brings me a healthy dose of anxiety and imposture syndrome. I believe educating others is the best way to strengthen one's knowledge and become an expert and it is my why for combating my anxiety! I have spent considerable time educating myself and working with national governing bodies to gain new knowledge to support and empower sites. Over the last five years, I have supported my professional development by conducting educational workshops and publishing articles related to clinical research at the national and international levels. During the COVID 19 pandemic, I published two articles discussing federal regulations for human research subjects and computerized systems during clinical research. I have provided over twenty live presentations either in person or via Webex as a shift in the pandemic to support my professional development. I also engage in podcasts and develop industry educational modules for clinical research sites. I worked with an international team to create a new education module for good clinical practice for Advarra and SCRS. During my engagement on the team, I was the only CRN. I was able to bring in my nursing knowledge to collaborate with the team to incorporate aspects of clinical research conduct that are unique to clinicians for education and learning modules—focusing on aspects of SAE & AE event reporting and informed consent. I provided a nursing perspective on assessing and collecting adverse event information with the human research subject. I also offered dialogue and guidance regarding nuances that CRNs face while conducting informed consent pre and post COVID. Using my clinical background and interprofessional communication skills, I collaborated with our team across the US, USA, and USA to network and support adding real-world case examples to the educational training modules for new clinical research members.
  3. **Professional and Ethical Practice:**

I was the lead clinical research nurse overseeing the integration of clinical research source records into our EMR across six-hospital health systems in USA. I utilized my knowledge of nursing practice and clinical research protocol to establish guidelines for information collected and placed into the EMR across a six-hospital health system to support our eSource records. Human research subjects are vulnerable, and information collected and studied about them is sensitive, and ethical consideration should be given to documentation in an EMR. We consider the long-term impact on subjects and studies that could potentially impact issues considering the types of trials we did not conduct in the current state. We identified sensitive categories of studies that would be retained behind a partition equal to that of behavioral health practices. Policy and law dictated that the partition records could only be summed by a court of law to disclose the sensitive details—establishing the partition allowed clinicians to be alerted that a patient was also a human subject for safety and oversight. As blinding procedures, protocol analysis, automated alerts, and programing were required, my ethical knowledge of how to oversee a human research subject and engagement with the fidelity of the protocol allowed me to oversee the project professionally and ethically.

* 1. **Team Focus and Interprofessional Collaboration:**

Human subject regulations and compliance are critical components of the CRNs skill set. The last three years have challenged me both personally and professionally as I have gained deepened knowledge regarding the federal and international regulations regarding the conduct of clinical research. I was tasked with understanding the USA national government structure while supporting over 200 hospital health systems' transition from paper-based processes into an electronic system. The project's overarching goal was to embed regulatory compliance across 200 sites while aligning and networking all teams into a centralized electronic structure. The challenge was that 200 sites practiced workflows and standard work instruction in distinct silos and could not concisely oversee all areas and align regulatory compliance for human subject protection. The prospect of learning new international regulations while applying my knowledge of US regulations was exhilarating and challenging. The project spanned 24 months, allowing me to become intimately familiar with the USA regulatory process and work closely with the national leadership teams representing the 200 sites. I collaborated with the state of USA to streamline the international regulations and accreditation requirements for the National Clinical Trials Governance (NCTG), leveraging the CTMS, eReg, eConsent, and eSource electronic systems. The CTMS established the NCTG framework tracking clinical trial operations from a clinical and business perspective and overseeing the key performance indicators to monitor and track outcomes associated with regulatory compliance and human subject protections. I believe that my professional growth came from learning new international regulations while also managing 200 distinct, disparate teams. Our teams were able to support the change management and implementation efforts of the 200 research sites into one consolidated electronic ecosystem. As you can imagine, in each of the site's practices, the conduct of research was slightly different. The challenge was using the electronic systems to streamline the clinical practice of all the nurses and providers across the state of New South Wales. Effective communication was critical to developing and adopting the new processes, policies, and procedures that we created within the electronic systems. This experience has deepened my knowledge and understanding of regulatory compliance and allowed me to strengthen my servant leadership by serving each of the 200 sites with empathy and patience. Shifting the course of a large team and successfully implementing an electronic infrastructure across 200 plus health systems has been a positive endeavor for my professional development and supported my international interprofessional collaboration as a clinical research nurse.

* 1. **Quality and Safety:**

I integrated quality and safety in various methods, leading the different teams mentioned above. The process I believe to be most important is the integration of computerized systems and regulations to support the conduct of clinical research sites. Engaging in CTMS, EMR, eReg, eConsent, eSource, and EDC offers our human research subjects increased quality and safety by leveraging technology across our teams. Technology enhances safety and oversight by making all aspects of clinical research conduct transparent and embeds safety checkpoints supporting the human element of tasks. I helped over 300 unique clients implement their technology stacks to pull data across all phases from start-up to close out and report on quality metrics that enhance the conduct of research and oversee the safe practice of human subjects. We created alert triggers to prevent a subject from receiving medications that could be excluded or considered harmful per the protocol improving safety and oversight while on the study. We also created embedded safety alert checklists to assess inclusion-exclusion criteria, improving screening accuracy while integrating safety reviews and oversight. Quality and safety are my why for engaging heavily in the technology side of clinical research to offer safe, quality trials to our human research subjects. I believe the work I am doing with technology using my CRN skill set is empowering CRNs across the globe. I am able to embed our nursing practice and CRN scope and standards into the development of technology software to empower CRNs and provide safety and oversight of the human research subject. I am blessed beyond measure to work in this capacity impacting research sites across the globe.

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