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Clinical Trial Research Nurse New Employee Onboarding 30- 60 -90 Day Checklist

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Abstract

Problem: The clinical trials research management team was plagued with high nurse turnover and poor clinical documentation due to a lack of seasoned clinical research nurses.

Context: A regional clinical trials team serving 22 hospitals within a Northern California not-for-profit health system.

Interventions: Mixed methods were used to inform the development of new employee onboarding for novice clinical trial nurses utilizing a structured 30-60-90 day checklist, improved communication channels, and continuous mentor support.

Measures: Monthly quality queries and quarterly staff turnover rates were tracked. Employee feedback was collected to assess the interventions' impact.

Results: The number of quality queries was reduced by 62.9% from 786 to 495, and the turnover rate decreased from 30% to 20% within the intervention period.

Conclusions: Structured and standardized onboarding and training for new clinical trial nurses can significantly increase knowledge, resulting in improved clinical trial documentation and reduced staff turnover rates. This project's success suggests that similar strategies can benefit other organizations facing high turnover and documentation quality issues. The interventions are scalable and adaptable, potentially leading to broader improvements in operational efficiency within a shorter timeframe.

Keywords: Clinical trials, research nurse, novice nurse, checklist, new employee orientation

Personal Leadership Statement

My vision for nursing leadership revolves around fostering compassionate and connected care by empowering and educating fellow nursing professionals to be competent and confident in themselves for their patients. This involves creating a supportive work environment that prioritizes education, offering a new employee training program, and encouraging career advancement to ensure compassionate and connected care. The clinical nurse leader (CNL) educator role demands innovation and a strategic focus on significant ideas while inspiring and educating other nursing professionals. It is essential to engage with the team, continually evaluate processes based on evidence-based practice, and enhance the value of staff duties for both them and the patients. Through this master's program, I have acquired the tools to strengthen my leadership skills and inspire others effectively. As Brené Brown said, "One day, you will tell your story of how you overcame what you went through, and it will be someone else's survival guide" (Brown, B., 2010). This project fulfills my vision of creating a new employee training checklist to advance our clinical trials research nurses from novice to expert while bestowing competence and confidence.

Problem Description

According to the National Institutes of Health (NIH), clinical research provides critical answers or information about diseases or how effective and safe a medication or therapy may be (National Institutes of Health, (NIH) 2015). Healthcare providers are essential to advising, guiding, and influencing patient participation in clinical research. Studies suggest that patients who receive information about clinical trials from their healthcare provider are significantly more likely to participate in a clinical research trial (Getz, 2017). With that knowledge, the Northern California health system created a centralized approach to clinical research that provides its members access to high-quality clinical trials (Kaiser Permanente, 2024b). The Clinical Trials

Program (CTP), developed in 2009, is a not-for-profit center serving the diverse communities in Northern California's San Francisco Bay area and supports the Division of Research (DOR). Established in 1964. the CTP is a centralized operational entity with multiple sites across the Northern California service region. This structure provides members access to high-quality clinical trials evaluating novel drugs and devices. Additionally, it facilitates access to therapies through Compassionate Use (CU), Humanitarian Use Devices (HUD), and Early Access Programs (EAP) (Kaiser Permanente, 2024b).

Comprehensive training for new employees is crucial to effective clinical trial management. The onboarding process is the initial introduction to the company's culture for new hires. A robust onboarding strategy emphasizes company values, promotes clear communication, and establishes expectations. Conversely, the absence of a structured onboarding process may convey to new hires that communication could be improved and that leadership may need to be fully committed to cultivating a positive work environment. As a result, 20% of new hires leave their position within the first 45 days (Llarena, M., 2013).

The CTP comprises thirteen Clinical Trial Research Nurses (CTRN). Since COVID, only three staff have remained. Turnover within this specialty significantly increases labor costs and impacts quality. Increased costs are attributed to the lag between onboarding and the time it takes for the new employee to acquire the basic skills needed to contribute to the organization (Forbes, 2020). Losing ten expert clinical trial nurses is costly and can significantly jeopardize the program's quality. Thus, a standardized onboarding and training program is needed to ensure adherence to Food and Drug Administration (FDA) Good Clinical Practice standards, which ensures ethical and high-quality care when working with clinical trial patients (US Food & Drug Administration (FDA), 2023). Standardized onboarding and training for new CTP staff provides fundamental knowledge standards for research nursing following the American Nurses Association Clinical Research Nursing Scope and Standards of Practice (American Nurses

Association (ANA), 2016). Conversely, if staff are well trained and feel valued in their work, they may be more inclined to stay, thus improving CTP retention.

To help advance these new clinical trial nurses from advanced beginners to expert research nurses (Benner,1999), a standardized approach to onboarding and training will be developed utilizing a simple checklist that provides a 30-60-90-day roadmap to ensure the new nurses are correctly trained and supplied with all the information necessary to be successful in their new role which can improve the quality of clinical research (Backman Lönn et al., 2022).

Specific Project Aim

This quality improvement project aims to reduce the number of clinical trial documentation quality queries by 10% from a baseline of 786 to 708 and reduce staff turnover by 10 % from 30% to 20% by July 2024.

Available Knowledge

PICO(T) Question

A population, intervention, comparison, outcome, and time (PICOT) question guided the literature search for this quality improvement project. The PICOT question was: In new clinical research nurses (P), how does developing and implementing a 30-60 90-day standardized checklist for onboarding (I) compared to the current orientation process of no standardized checklist (C) improve retention, satisfaction, and quality (O) by July 2024 (T)?

Search Methodology

A systematic electronic search was conducted of articles from different databases: PubMed, CHINAHL, Evidence-Based Journals, and Cochrane Database of Systematic Reviews. The search strategy was focused on research nurse training (CRN) and employee retention. Search terms included *research training, retention, clinical trial standards, and research nurse "CRN*." The search was further limited to English articles from 2013 to the present. Nine articles were retrieved as a result of the search. These nine articles were initially

reviewed by reading the title, the abstract, the design, and the methodology. Additional criteria were articles that showed standardized training with associated retention data. The selection was narrowed to five articles that had applicability to the project. Articles were appraised using the Johns Hopkins Nursing Evidence-Based Practice Tool (JHNEBP) (see Appendix A).

Integrated Review of the Literature

Three primary themes emerged from the review of the evidence. First, it is vital to adequately onboard new employees by incorporating standard training programs with essential elements, including measures for success (Gow et al., 2021). Secondly, the evidence supported using standardized checklists to help train novice nurses and reduce human error in more proficient nurses (Gawande, A., 2010). Third, establishing the basic standards of research nursing using a standardized and systematic approach will ensure a smoother transition into this non-traditional nursing role (Herena et al., 2018; Backman Lonn et al., 2022).

Backman Lonn et al.,2022, conducted semi-structured qualitative interviews of ten clinical research nurses in 2017 to explore the lived experience of nurses in Sweden who were transitioning into non-traditional clinical research nurse roles. Participants were interviewed about their experience working in a new role, ethical dilemmas, and organizational and professional issues related to the role. The interviews were analyzed inductively using qualitative content analysis. Analysis revealed that the nurses experienced some reality shock when they became clinical research nurses as they found the role to be both challenging and a transformative experience. The central theme was that becoming a clinical research nurse was a difficult transition. The new role was less defined than their previous nursing role, and they struggled to regain their new professional identity. The nurses also grappled with new extended professional mandates, such as increased professional status and an expanded ethical consciousness as part of their new role (Backman Lonn et al., 2022). The researchers concluded that registered nurses who became clinical research nurses had needs distinct from

and overlapping those of their former professional role as registered nurses. To smooth the transition, they recommend the development of clear training pathways that include an introduction to the role, mentorship, and continued support as they move from novice to expert. This study was rated as a Level III A study and has important implications for this quality improvement initiative, which seeks to standardize the onboarding of new clinical trial nurses, which, according to Backman Lonn et al., 2022, can reduce culture shock and improve role identify as a clinical trial nurse moving from novice to expert.

To provide a roadmap for training, Boston surgeon Atul Gawande explored why intelligent people make avoidable mistakes. In the "*Checklist Manifesto,"* Dr. Gawande advocates using checklists in professions like medicine, aviation, and construction to prevent errors caused by human fallibility exceeding individual capacity. Despite extensive training, expertise alone cannot eliminate mistakes; thus, checklists provide a crucial safety net for error prevention (Gawande A., 2010). According to Dr. Gawande, checklists help prevent failure by addressing two problems: memory and attention to detail, which fail when we are distracted by more urgent matters, and people tend to skip steps even when they remember them (Gawande, A., 2010). Checklists remind you of the minimum necessary steps. Dr. Gawande's work follows the publication of the World Health Organization (WHO) checklist results in early 2009, in which over a dozen countries committed to adopting checklists. By the conclusion of 2009, approximately 10 percent of hospitals in the U.S. and 2,000 globally had either implemented or pledged to implement the checklist. Despite the documented success of checklists in preventing errors, it remains a challenge to persuade healthcare providers to change from a go-it-alone mindset beginning with the adoption of checklists. As Dr. Gawande points out, if clinicians adopted and embraced this change, checklists would become as essential as stethoscopes are to daily practice (Gawande, A., 2010). Thus, the work by the WHO and Dr. Gawande supports the use of a checklist as a means to

improve safety and supports the development of training checklists that will aid in onboarding new clinical trials personnel to ensure crucial essential information and steps are not missed.

Using the ANA's scope and standards of practice for clinical research, Herena et al. (2018) demonstrated the benefit of utilizing these standards to create training tools to decrease nurse turnover and facilitate the transition of new clinical research nurses to their roles at one comprehensive cancer center. The impetus for the project was to address the shortage of clinical research nurses and address a turnover rate that had skyrocketed to 28% by early 2017, leaving few CTRNs to cover the growing number of research studies and train new staff. These heavy workloads have decreased staff morale and negatively impacted the quality of care and rigorous practices needed to maintain the integrity and quality of clinical research. The training course developed from the ANA scope and standards for clinical research nurses was implemented in late 2017, resulting in a reduction of nurse turnover from 28% to 5.9% in the subsequent quarters post-implementation, and has been maintained at that level ever since. This quality improvement project validates the need for structured onboarding focusing on the specialty of clinical research nursing.

In conclusion, onboarding nurses in new fields requires structured and standardized processes that incorporate standardized checklists to prevent errors coupled with specialized curricula based on ANA's scope and standards of practice. These two strategies will augment the transition of clinical research nurses entering the specialty while reducing burnout and turnover in the more experienced staff who must support the training and mentoring of these novice clinical research professionals.

Rationale

Benner's (1982) novice-to-expert framework is the selected framework that will be utilized to assess and evaluate nurses' training methods and proficiency levels within the clinical trials unit. Rooted in the Dreyfus model of skill acquisition, Benner's framework applies a developmental perspective to nursing practice, drawing parallels between the stages of skill

acquisition and the progression from novice to expert (Benner, 2004). Conceptualized initially for fields such as chess and aviation, the Dreyfus model posits a trajectory of learning that traverses five distinct phases. Similarly, Benner's model delineates these stages of competence within the nursing context: novice, advanced beginner, competent, proficient, and expert, each stage representing a continuum of skill development building upon prior levels (Benner,1982).

Beginning with a reliance on rules and task-oriented approaches, nurses progress through the five stages through exposure to diverse experiences, gradually reducing dependency on prescriptive methods and cultivating the capacity for nuanced problem-solving. This evolutionary skill acquisition process is integral to nursing education and professional development (Papathanasiou et al., 2014). Practical applications of this framework include using structured tools such as checklists, which are particularly beneficial for novices navigating unfamiliar terrain (Ghasemi et al., 2020).

Recognizing the inherent lack of experience among new clinical trial research nurses, implementing standardized training checklists is a salient component of quality improvement endeavors. These checklists provide a navigational aid to compensate for novice-level proficiency.

Context

Department of Research (DOR) is a not-for-profit organization serving the San Francisco Bay Area's diverse communities. It covers multiple sites and reports no new employee training SOP. The DOR comprises 600-plus staff working on more than 454 field epidemiological and health services research projects (Kaiser Permanente, 2024a). The DOR staff includes doctors, nurses, medical assistants, laboratory assistants, phlebotomists, scientists, IT, database monitoring, quality, clinical research associates, clinical research coordinators, and management staff. Departmental hours of operations are Monday through Friday, with some Saturdays. Some staff work full-time, while others are part-time or temporary work on a

particular clinical research protocol. All staff are competent in many databases, have technical skills, and hold licenses or certificates in higher education.

Many tools were used to help inform this quality improvement initiative, including a gap analysis, a GANTT chart, a SWOT analysis, a power grid analysis, and a budget analysis.

Gap Analysis

A gap analysis identified the following opportunities to improve staff onboarding and skill acquisition, which include training of staff on new electronic checklists to reduce time to study activation, use of standardized “smart” phrases in EMR to improve documentation, standardized onboarding based on the ANA scope and standards for clinical research nurses (see Appendix B). To achieve these goals, this master student, a Clinical Nurse Leader (CNL), performing the roles of outcomes manager and educator, was essential in developing and implementing an evidence-based quality improvement project of a standardized training checklist within the CTP microsystem. The successful implementation of this quality improvement initiative will maximize resources, mitigate risk, and reduce rework from documentation errors. This improvement project will use evidence-based practice to implement a new employee onboarding (NEO) that consists of a 30-60-90-day checklist, a satisfaction survey to monitor current satisfaction and confidence of the registered nurses, a pretraining, a 30 & 60-day and post-training surveys to ensure proper training. Data collection will include the number of quality queries incurred, nurse retention, and turnover. The project is anticipated to lead to improved quality of clinical research trial outcomes and reduced staff turnover. These outcomes align precisely with the organization's and microsystem's mission: to transform health through research and find the best ways to deliver health care to members and society (Kaiser Permanente. 2024b).

GANTT Chart

A Gantt chart depicts the project timeline (see Appendix C). The project began with a gap analysis and identified the need for the project. Critical milestones for the project included

the presentation to the senior learning consultant for The CTP in January 2024. Approval for the project occurred in March 2024, and the data collection began for staff numbers and hire dates, retention numbers, quality queries, and any NEO onboarding. Data collection concluded in May 2024. Next, a staff survey was created to identify staff perception of the role, including job satisfaction and pretraining needs 30-60 into training. The employee job satisfaction survey results were used to help create the NEO checklist and SOP for CTRNs. Once the checklist and SOP were approved, they were used to retrain the last two CTRNs hired. This retraining occurred from May 2024 through July 2024. Once training was completed and evaluated, the NEO checklist was provided to all CTRNs as a reference. Finally, the job satisfaction survey was sent out again to measure nurse satisfaction and confidence in the job duties post-project implementation. Key milestones for the project are highlighted in a project timeline (see Appendix D).

SWOT Analysis

A strengths, weaknesses, opportunities, and threats analysis were used to identify the internal and external variables influencing the microsystem's implementation of CTRN NEO training (see Appendix E). Strengths include strong teamwork, highly educated staff, an extensive database of patients for clinical research, and commitment to quality improvement, which will support this project. Additionally, the existing use of Viewpoint software by all members of the healthcare team and the need for NEO training implementation are supporting factors.

Weaknesses may include staff resistance to new training, low job confidence that the implementation of training will affect their job satisfaction or patient outcomes, and costs associated with implementing and measuring these outcomes.

This project's opportunities include the potential to increase job confidence, create an NEO checklist, reduce data errors, improve quality standards and job satisfaction, improve trial

outcomes, and advance the hospital's training technology to remain competitive with other organizations. Finally, threats to this project may include internal factors such as the new management system not working as described, costs associated with digital training creation, and employee training.

Power Grid Analysis

Critical stakeholders for this project include this CNL student, the department manager, quality staff, IT staff, and the director. This CNL student was responsible for conducting the microsystem financial assessment, selecting the project focus, drafting the project plan, and identifying key stakeholders. The department reviews and approves the proposed project and associated costs. Once approved, this student CNL met with the team to ensure everyone understood the project and their role and responsibilities. Next, the SOP checklist was developed with input from the quality manager. Once the feature was released, the CTRNS were educated on how to use the tool. Data was collected while the tool was used, and monthly analytics reports were collated to update the team and stakeholders on the results. Finally, the CNL evaluated the project outcomes and worked with the manager to finalize the training. The project intervention period ran from January 2024 through July 2024. Consistent evaluation of outcomes and fine-tuning of the NEO continues. (see Appendix F).

Interventions

This quality improvement initiative employed qualitative and quantitative methodology to address the high turnover and high-quality queries within the Department of Research (DOR) microsystem. As previously defined, the project's goal was to implement a comprehensive onboarding program that covers all aspects of clinical trial management, including company values, regulatory compliance, and specific protocols, using a 30-60-90-day training checklist. This improvement project used evidence-based practices to address job retention, job

satisfaction, and job confidence of novice clinical trials registered nurses. The project was piloted with the two most recent CTRNs hired.

The tools incorporated for this intervention were based on the qualitative data obtained from two baseline surveys created in Microsoft Forms® and administered electronically. They included an employee satisfaction survey (Appendix G) and a NEO pre-training survey (Appendix H). The NEO survey was administered again at 30 and 60 days to allow staff to provide additional feedback on what other content may have improved the training experience and monitor progress (see Appendix I). A final post-training survey was created and administered to obtain additional feedback at the end of the onboarding process (see Appendix J). Feedback was solicited from all current staff (n=13) for the employee satisfaction survey, and the remaining surveys were completed by the novice CTRNs (n =2). Feedback from both groups was useful in informing the tool development, including the NEO onboarding and training checklist (see Appendix K). The ANA clinical nursing scope and standards of practice for Clinical Trials nurses provided the ethical and theoretical foundation on which these tools were developed. Additionally, feedback identified the need for standardized “smart phrases” created and used within the electronic health record (EHR) to increase job satisfaction, improve confidence, and help decrease data entry errors. The survey results also identified the need for a clinical trial standard operational workflow (see Appendix L). The checklist and other educational materials were loaded onto KP Learn™ for asynchronous learning, including Collaborative Institutional Training Initiative (Citi) training. Each trainee was given the ANA Clinical Research Nursing Scope and Standards of Practice guidelines book to read as a key training component.

Mentorship was integral to training and developing new research nurses for this project. To create a more cohesive team and improve collaboration, novice nurses were assigned to one of the onsite managers as the primary mentor. This CNL student held weekly check-ins with

pilot employees to address concerns and provide continuous support during the new training program. Feedback and evaluation of the processes and materials tested by the pilot group were analyzed and recommended changes were incorporated and introduced to the rest of the CTRN staff to level set knowledge and practice expectations. This helped foster a positive work environment and provide opportunities for professional development and career growth to retain talented staff, reduce errors in documentation, enhance overall data quality, and encourage a culture of quality and accountability.

To implement this improvement project, the team employed a Clinical Nurse Leader (CNL) student, a senior learning consultant, quality staff, a department manager, and a director. The CNL student coordinated and executed the development of the training checklist to reduce nurse turnover, ensure improved regulatory-compliant documentation with fewer Federal Drug Administration (FDA) violations, and improve job confidence and job satisfaction.

Budget Analysis

The financial model for this project is primarily aimed at cost avoidance from reduced staff turnover. The aim is to increase CTRN retention and decrease quality queries, which is anticipated to save $1,565,563 annually. Budgetary assumptions informing this project included the average yearly CTRN salary of $266,000, including benefits and proper onboarding, which takes approximately one year and includes the standardized 90-day onboarding program. The project implementation cost is estimated at $147,678, for a total net cost savings of $1,417,885 (see Appendix M).

Study of the Intervention

Due to the great resignation of 2021(World Economic Forum, 2021),10 of the 13-member team was new to CTP. Five new nurses (45%) had not received formal training or had prior clinical research experience. As a result, poor data quality was adversely impacting the overall efficacy and efficiency within the department. A standardized onboarding and training for

new CTP staff that provides a fundamental knowledge standard for research nursing within the American Nurses Association Clinical Research Nursing Scope and Standards of Practice (ANA, 2016) was developed and implemented to overcome this challenge. Well-trained staff who feel valued in their work may be more inclined to stay, thus helping increase CTP retention. By implementing these measures and continuously monitoring progress, the project aimed to achieve a 10% reduction in clinical trial documentation quality queries, a 10% reduction in staff turnover, and better job satisfaction by July 2024.

The interventions for this project included outcome, process, and balance measures defining the project, which are delineated in the Project Charter (see Appendix N). The quality data results were received through the Appian Risk-Based Monitoring Application, the department's internal monitoring system. This system tracks IRB reportable violations and FDA compliance. Retention data was received from HR to track employee employment. Job satisfaction was tracked using pre-, during-, and post-training surveys.

Ethical Considerations

The project aligns with Jesuit values of Cura Personalis and Faith in the Service of Justice and ANA Ethical Standards Provision Five: Competence and Professional Growth and Provision Seven: Advancing the Profession. Provision Five of the ANA Code of Ethical Standards focuses on education, professional development, and ethical practices in clinical research nursing. The project's emphasis on enhancing the education of clinical research nurses reflects a commitment to excellence. By improving the knowledge and skills of these nurses, the project aims to ensure high standards of clinical research and patient care. Provision Seven of the ANA Ethical Standards: Advancing the Profession supports maintaining competence and pursuing professional development of nurses who participate in clinical research. Offering educational resources and training helps nurses enhance their competencies and supports their ongoing professional growth (American Nurses Association, 2015).

Enhancing education and professional development directly relates to the Jesuit commitment to Care for the Whole Person (Cura Personalis), ensuring that leaders' and staff's anonymity and participation are respected and maintained. This consideration for personal dignity aligns with the Jesuit value of caring for the whole person. Faith in the Service of Justice is shown by the project's priority of justice and equity by providing quality education and professional development opportunities for clinical research nurses. This focus ensures that all nurses have access to the resources and knowledge needed to perform their roles effectively, promoting fairness and justice in the workplace.

The project's Ethical Considerations include Beneficence, Justice, Confidentiality, and Anonymity. The principle of beneficence applies across the broader healthcare community and ensures goodness by improving nursing practice and patient outcomes. The project ensures justice and fairness by providing access to educational resources and professional development opportunities for all clinical research nurses, regardless of their background.

The project's design, rooted in justice and equity, ensures that all clinical research nurses have equal access to development opportunities, reflecting the Jesuit principle of faith in the service of justice and the ANA's commitment to fairness and professional advancement.

The project maintained strict confidentiality and anonymity standards, protecting participants' identities. This ethical consideration is crucial in respecting the privacy and dignity of the individuals involved. Maintaining voluntary and anonymous participation in the project demonstrates respect for individual autonomy and privacy and critical ethical principles grounded in Jesuit values and the ANA Code of Ethics.

In conclusion, the project aligns with and actively embodies Jesuit values and the ANA ethical standards by implementing high-quality education with equal access for all participants while adhering to the ANA Code of Ethics to promote clinical research nurses' professional growth and development. These principles are integral to the project's design and

implementation, ensuring that it upholds the highest ethical standards while contributing to advancing the nursing profession. USF faculty approved this project as a quality improvement project using QI review guidelines, and it does not require IRB approval (see Appendix O). Additionally, the organization's Research Determination Office (RDO) has reviewed the project and determined that it does not qualify as research (see Appendix P).

Outcome Measure Results

Quantitative Results: Quality Queries

Quantitative analysis of clinical trial documentation quality queries post-implementation saw a decrease in errors by 62.9% from a baseline of 786 to 495 by July 2024 (see Appendix Q). The average number of quality queries per quarter before the intervention was 196 (786/4). Post-intervention, it dropped to an average of around 124 queries per quarter. A line graph shows a downward trend in quality queries over time, with notable reductions coinciding with key intervention milestones. The improvement in documentation quality suggests that the new onboarding and training processes were effective, leading to more accurate and compliant data management in clinical trials.

Qualitative Results: Employee Survey

Two employees were administered employee surveys at pre-training, 30 days, 60 days, and post-training. The two most recently hired CTRNs completed the surveys. The pre-training survey was the baseline for comparing subsequent data (see Appendix R). Only one employee expressed extreme dissatisfaction regarding where to go and what to do on the first day. Employee feedback indicated a clearer understanding of documentation standards and better protocol adherence post-project implementation surveys administered at 30 and 60 days (see Appendix S). The post-training survey results showed improvement in all these areas, with one nurse identifying the need for additional education on ethical principles as they apply to clinical

trials (see Appendix T). The common themes identified included a lack of knowledge and support for the novice clinical trials nurse. The initial employee satisfaction survey completed by all staff (n=13) identified workflow gaps, quality queries, how to resolve them, CTRN roles and responsibilities, orientation and training, and improved management communication (see Appendix U). All post-surveys revealed improved job satisfaction and a stronger sense of belonging among CTRN employees.

Quantitative Results: Staff Turnover Rate

Reduced staff turnover rate by ten percentage points, from 30% to 20%, by July 2024. The entire CTP met this outcome. CTRN turnover was 0%. All 13 CTRNs from 2022 remain in July 2024 (see Appendix V). This significant decrease in turnover suggests that the interventions successfully addressed the key factors contributing to staff dissatisfaction and turnover. Enhanced onboarding, clear communication, and continuous support were instrumental in retaining employees.

Summary

This quality improvement project achieved its goals by significantly reducing clinical trial documentation quality queries and staff turnover rates through comprehensive onboarding, training programs, and continuous support. Quantitative and qualitative analyses confirm the effectiveness of these interventions, demonstrating a positive impact on documentation quality, employee retention, and job satisfaction.

The interventions implemented included enhanced onboarding and training programs, improved communication channels, and continuous support mechanisms. These interventions were directly associated with the observed outcomes of reduced clinical trial documentation quality queries and decreased staff turnover rates. The enhanced onboarding process provided clear guidelines and expectations, while the improved training ensured that employees were

well-prepared and knowledgeable about their roles. Improved communication channels facilitated better support and feedback, increasing job satisfaction and retention.

The findings align with existing literature emphasizing the importance of comprehensive onboarding and training in improving job performance and reducing turnover. Studies have shown that effective onboarding programs lead to higher employee engagement, better job performance, and reduced turnover rates. (Forbes, 2020) Our results support these findings, demonstrating significant improvements in documentation quality and employee retention following targeted interventions.

Impact on new employees showed improved job satisfaction, better understanding of roles, and enhanced engagement. There was a smoother transition into the company, leading to increased confidence and productivity. This reduced the management burden of high turnover rates and fewer quality queries. Adherence to documentation processes enhanced accuracy and compliance in clinical trial documentation. Reduced turnover led to fewer disruptions and more stable team dynamics, which fostered a culture of continuous improvement and accountability.

Strong leadership support and commitment to the project contributed to the successful outcomes. High levels of engagement and participation in the new program facilitated the changes. Any external factors might have influenced the outcomes but were not accounted for in this project.

The results of this initiative were specific to the context of this particular organization and its unique culture, structure, and operational environment. The interventions may yield different outcomes in different settings, such as organizations with different sizes, industries, or employee demographics. Other simultaneous organizational changes or external factors that could have influenced the outcomes of this initiative were not identified or controlled for, thereby

affecting the generalizability to other healthcare organizations, including selection bias since the sample of new hires was not representative of the overall employee population. Efforts made to minimize and adjust for limitations ensured consistent application of the onboarding and training programs across the department. Continuous tracking of progress and feedback to adjust strategies were incorporated as needed. Where possible, every effort was made to account for other variables that could impact the outcomes, such as departmental differences or external economic conditions.

Conclusions

The quality improvement project demonstrated significant improvements in clinical trial documentation quality and staff turnover rates through targeted onboarding, training, and communication interventions. While the results are promising, the generalizability is limited to similar organizational contexts. The project highlights the importance of continuous monitoring and adaptation to ensure sustained success and to address any emerging challenges or limitations. Enhanced accuracy in documentation and reduced turnover lead to more stable and efficient operations. Comprehensive onboarding and continuous support foster a positive work environment, increasing job satisfaction and retention. Better documentation practices ensure compliance with regulatory standards, reducing the risk of audits and penalties.

Integrating the new onboarding program into standard operating procedures can sustain these practices over time. Regular feedback and monitoring ensure the processes remain relevant and practical, allowing for ongoing adjustments and enhancements. The interventions can be adapted and scaled to other domains within the organization. Similar organizations, particularly those involved in clinical trials, can adopt these practices to improve documentation quality, employee retention, and job satisfaction.

Providing thorough onboarding and continuous support aligns with person-centered care principles, as it addresses the needs and well-being of employees. Improved documentation

quality benefits patient safety and care by ensuring accurate and compliant data management in clinical trials. Proper training ensures that employees are well-prepared to handle their responsibilities, leading to higher quality and safer practices. Fewer quality queries indicate reduced errors and inconsistencies, contributing to overall quality and safety in clinical trial management. Accurate and high-quality documentation improves the reliability of the clinical trial data, which can lead to more effective treatments and improved population health outcomes.

The suggested next steps are to (a) conduct a deeper analysis of other clinical trial roles that need improved onboarding and training programs, (b) adapt and implement this program for those roles in need, (c) disseminate the findings and best practices with other organizations (d) establish a continuous feedback loop with employees to ensure ongoing improvements and adjustments to the onboarding program, (e) regularly review and update the program based on evidenced bases standards and employee feedback, (f) monitor the quality queries and turnover rates over a more extended period to ensure sustained improvement and identify any new challenges.

Organizations facing high staff turnover and quality issues in documentation can benefit from investing in comprehensive onboarding, providing continuous support, and fostering a positive culture. By adopting similar strategies, other organizations can achieve improved employee retention, enhanced operation efficiency, and better compliance with regulatory standards, ultimately leading to higher quality and safer practices in their respective fields.

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Appendix A

Evaluation Table

PICOT Question: In new clinical research, nurses (P) Does developing and implementing a 30-60 90-day checklist for onboarding (I) compared to the current orientation process (C) improve retention, satisfaction, and quality (O) by July 2024 (T)?

Study	Design	Sample	Outcome/Feasibility	Evidence Rating
Benner, P (1982) From Novice to Expert Source: *The American Journal of Nursing*, Vol. 82, No. 3 p. 402-407  Benner-NoviceExpert-1982.pdf	Expert opinion	none	Useful for providing theory for novice to expert	V A
American Nurses Association (ANA). (2016). *Clinical Research Nursing: Scope and Standards of Practice* (1st ed.). American Nurses Association, Inc. https://www.wolterskluwer.com/en/solutions/ovid/clinical-research-nursing-scope-and-standards-of-practice-14176	Expert opinion	none	Nationally recognized scope and standards for practice	IV A
Gallup Perspective on Creating an Exceptional Onboarding Journey for your new employees(n.d.)  Gallup_Perspective_on_Creating_an_Exc	Expert Opinion	None	the essential elements of an onboarding program	V A

Gawande, A. (2010). The checklist Manifesto How to get things right., Metropolitan Books ISBN:9780312430009  AtulGawandeTheC hecklistManifestoH(	Expert opinion	none	The book builds the case for checklists and issues a plea for adopting this backstop to human fallibility.	IV A
Gow, H., Ollom, C., Rowell, M., Ryder, M., & Zanvill, N., (2021) Onboarding experienced non-oncology nurses to address staffing shortages. v36n4-onboarding-experienced-non-oncology-nurses-to-address-staffing-shortages.pdf (accc-cancer.org)  onboarding-experi enced-non-oncolog	Qualitative	None	developed metrics for success, monitored outcomes, and communicated results to drive support for the initiative and helped improve the program.	IV A

Herena, P. S., Paguio, G., & Pulone, B. (2018). Clinical Research Nurse Education: Using scope and standards of practice to improve care. *Clinical Journal of Oncology Nursing*, *22*(4), 450–452. https://doi.org/10.1188/18.CJON.450-452  clinical research nurse education.pd	qualitative	none	research nurse leadership team created a course using the clinical research nursing scope and standards of practice. The results validated the need for this course and supported plans to continue to provide the course to new hires.	IV A

Hernon, O., Dalton, R., Dowling, M. (2020) Clinical research nurses' expectations and realities of their role: A qualitative evidence synthesis. *J Clin Nurs*.;29:667–683. https ://doi.org/10.1111/jocn.15128  Clinical research nurses expectation	Qualitative synthesis	none	This review highlighted the many challenges faced by clinical research nurses and their need for education, especially in the role transition phase, where education should focus on the clinical research nurse's responsibilities in terms of trial integrity.	IV A

Lönn, B., Hörnsten, Å., Styrke, J., & Hajdarevic, S. (2022). Transitioning to the clinical research nurse role – A qualitative descriptive study. *Journal of Advanced Nursing*, *78*(11), 3817–3829. https://doi.org/10.1111/jan.15397  Journal of Advanced Nursing -	Qualitative descriptive study	10 RN's	Results used to strengthen the role of CRNs, improving the quality of clinical studies conducted in Sweden. Providing customized education and support to RNs to transition into the CRN role improving their competence. Offering mentorship and introductory training, courses on the research process, ethics, project coordination, leadership and communication.	III A
Sonstein, S. A., Silva, H., Jones, C. T., & Bierer, B. E. (2024). Education and training of clinical research professionals and the evolution of the Joint Task Force for Clinical Trial Competency. *Frontiers in Pharmacology*, *15*, 1291675. https://doi.org/10.3389/fphar.2024.1291675  education and training of clinical r	Expert Opinion	None	early recognition of the professional roles and their importance and competency standards defining the work, educational pathways, and professional development paths for trial competency.	V B
World Economic Forum. (2021). *What is the "Great Resignation?" An expert explains*. https://www.weforum.org/agenda/2021/11/what-is-the-great-resignation-and-what-can-we-learn-from-it/  What is The Great Resignation and wh	Qualitative-expert opinion	None	The Great Resignation is a phenomenon that describes record numbers of people leaving their jobs after the COVID-19 pandemic ends.	V B

Appendix B

Gap analysis

Gap Analysis		
Area under consideration: Clinical research nurse training program NEO		
Desired State	Current State	Action Steps
Less duplication due to new system-Signal Path/Verily	New clinical trial management program -Signal Path/Verily	Roll out of new system, currently in roll-out process
IRB approval 30-90 days	IRB approval review 6 months	??
All trials have smart phrases developed for all listed activities	New development of smart phrases for documentation to lower queries from quality and sponsor and avoid IRB reporting	New trials CTRN making smart phrases for all staff
SIV to kick off 30 days	Sponsor initial visit to kick off 90 days	IRB, smart phrases, finance
SOP-30-60-90-day checklist	None-self-taught	Develop training checklist
Training-EDC, signalpath/verily-study activities, e-binder, adobe sign, study supplies, IRB expectations	None-self-taught	Develop training
Training-study logistics – protocol questions, pharmacy, lab, SIV, recruitment, screening, day one	Self-taught-none	Develop Training
Training-education, development expectations, HR connect tracking	PPT presentation done by Susie Um that is generalized to ALL positions at DOR	Develop program for CTRN specifically

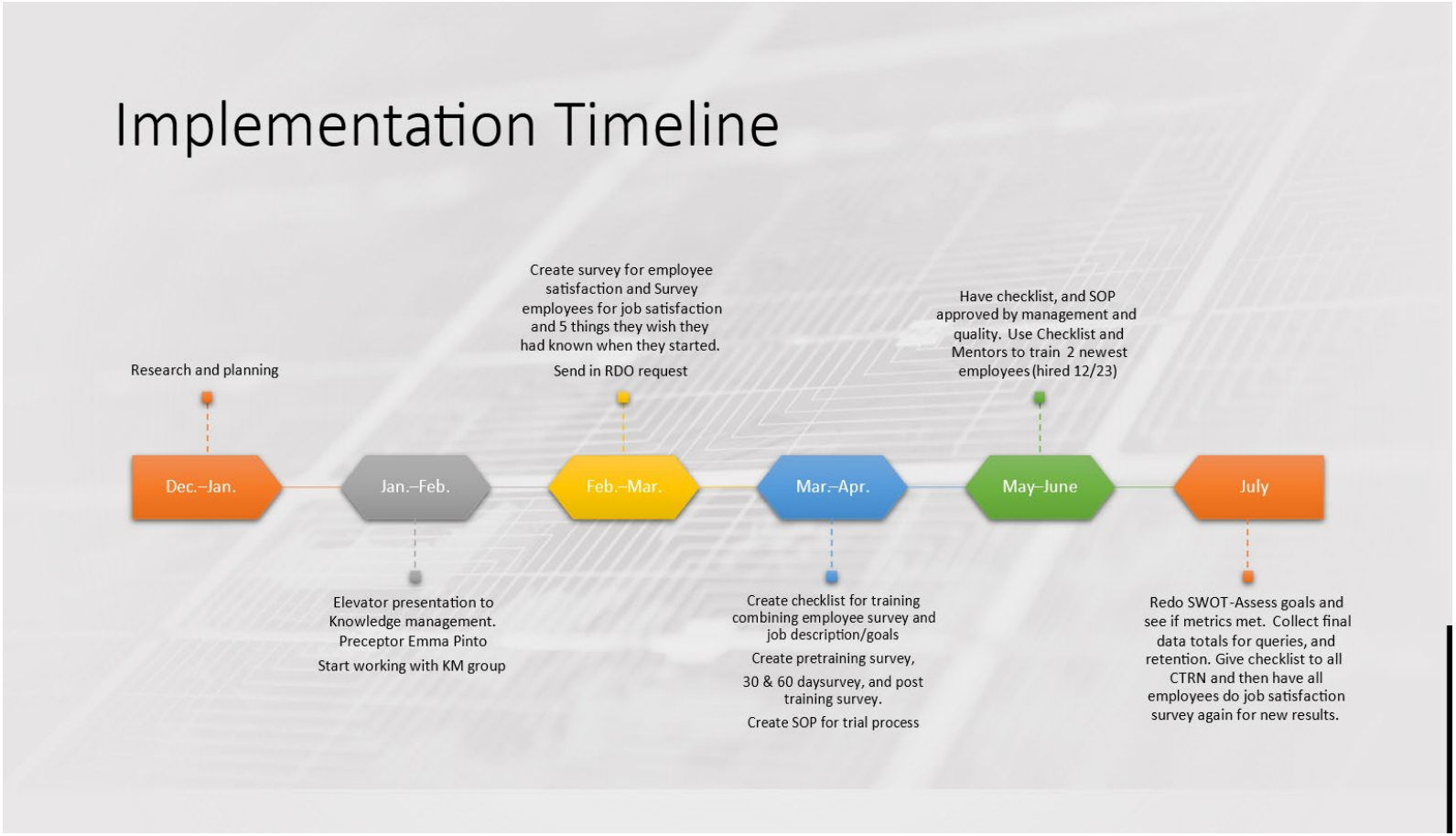
Appendix C

Gantt Chart

Task #	Description of Tasks and Communication Interventions	2024 DEC	Jan	Feb	Mar	2024 April	May	June	July	Aug	Responsible Party/Stakeholder	Status
1	Conduct Microsystem assessment										CNL-MSN student	Completed
2	Discuss rationale at Clinical Trial Monthly Meeting to create training 30-60-90day checklist (checklist manifesto-SOP)										CNL-MSN student, Manager, Director	Completed
3	Pitch idea to Senior learning consultant										Sr learning consultant (SLC), CNL-MSN student	Completed
4	Create employee satisfaction survey and survey CTRN's										CNL-MSN student, SLC, CTRN's	completed
5	Create Checklist, workflow, and pre training survey										CNL-MSN student, Senior CTRN	completed
6	Leadership approval of checklist and workflow										SLC, manager, director	completed
7	NEO Kick off training Pilot group (last 2 CTRN hired) and pre training survey given										CNL, Knowledge managent group, leadership	completed
8	Weekly teams meetings to evaluate progress and changes needed with Pilot CTRN's and Knowledge management group										CNL, Knowledge managent group, CTRN	completed
9	Collection of HR and Quality Query data for baseline										Quality, IT, HR, CNL	completed
10	Creation of 30-60 and post training surveys										CNL	Completed
11	30 and 60 day surveys given to pilot group										CNL, CTRN	Completed
12	creation of post training survey										CNL	Completed
13	post training survey given to pilot group										CNL, CTRN	Completed
14	collection of HR and Quality Query data for final measurement										Quality, IT, HR, CNL	Completed
15	Debrief with pilot group to obtain feedback and recommendations for change to finalize documents for department use										CNL, CTRN's	Completed

Appendix D

Project Timeline



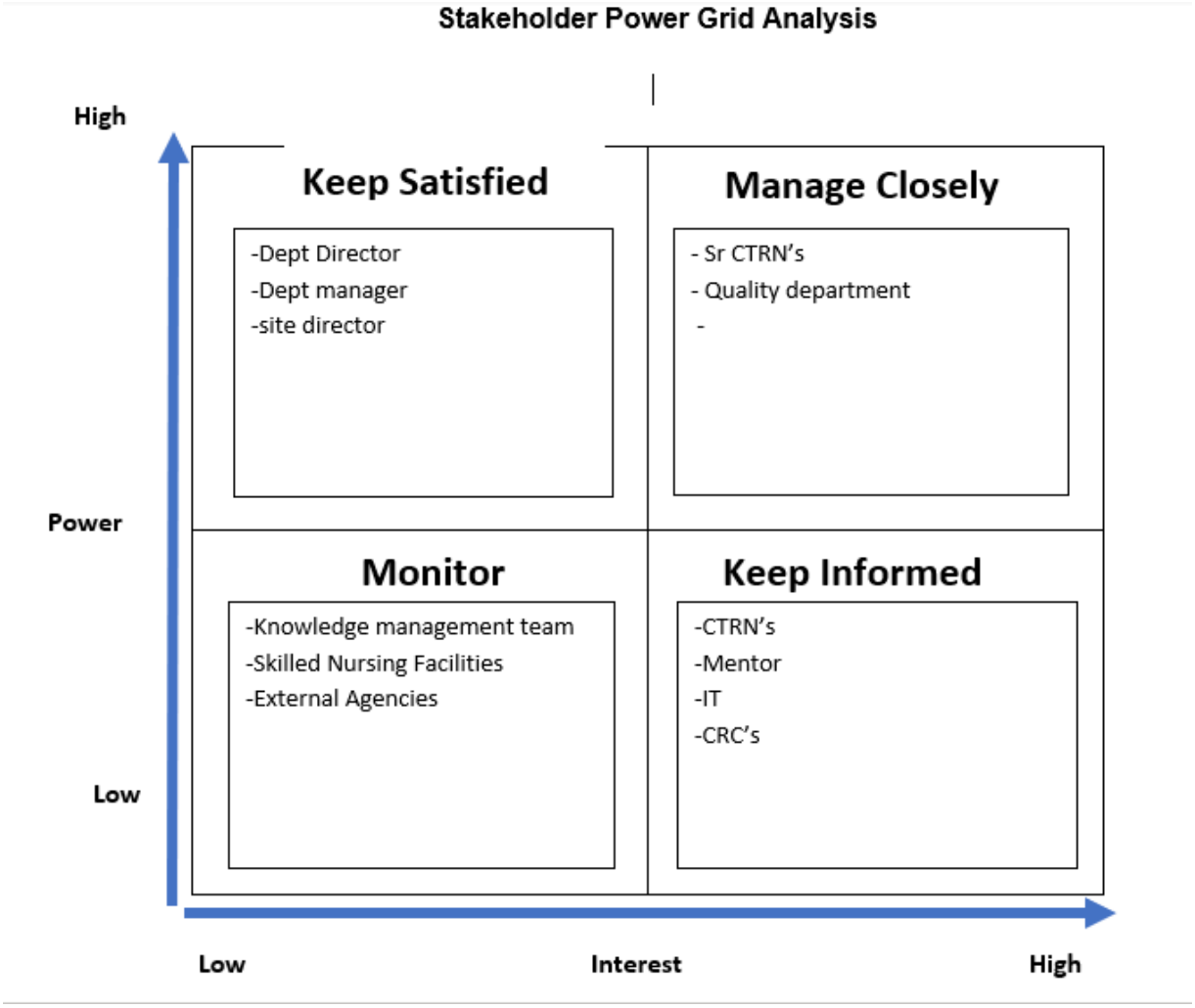
Appendix E

SWOT analysis

	Favorable/Helpful	Unfavorable/Harmful
Internal (attributes of the organization)	**Strengths** • Highly educated persons delivering innovative care. • Encourage EBP • Large database of patients for clinical research. • better financial monitoring of trials through signal path • working Teams in place • Use of mentors	**Weaknesses** • No new employee onboarding standardization • Sponsor and quality queries. • At risk for IRB/FDA reporting • No Integration of multiple systems • Retention • Possible low Job confidence
External (attributes of the organization)	**Opportunities** • New Clinical Trial management software • New NEO onboarding website • Smartphrase development • New CTRN's • Coordinate professional goals with training program. • Digital training development • Increase job confidence. • NEO checklist creation • Reduce quality queries.	**Threats** • The new clinical trial management system not working as described. • Post covid workplace. • FDA or IRB • Lack of coordinated training • Low job confidence • Trial patient retention • CTRN retention • Costs associated with training.

Appendix F

Power Interest Grid



Appendix G

Employee Satisfaction Survey

Employee Satisfaction Survey (2)

This is a survey for employees of The Clinical Trials Program (CTP). The aim is to understand the working conditions, training, professional expectations, and overall job satisfaction of all our team members. Your feedback is anonymous. Filling in the survey should take you a maximum of 5-10 minutes.

1. How long have you been working for Kaiser?

	<1 year	1-2 years	2-5 years	6-10 years	10+ years
Statement 1	◯	◯	◯	◯	◯

2. How long have you worked for the CTP?

	<1 year	1-2 years	2-5 years	6-10 years	10+ years
Statement 1	◯	◯	◯	◯	◯

3. What is your job title?

- ◯ CTRN
- ◯ CRC

4. Please rate your satisfaction with the following aspects as an employee at the CTP

	Extremely Dissatisfied	Dissatisfied	Neutral	Satisfied	Extremely Satisfied	Not Applicable
Your job overall	○	○	○	○	○	○
Understanding of your role and responsibilities.	○	○	○	○	○	○
A well-organized list of trainings was provided when you started.	○	○	○	○	○	○
The trainings you received when you started prepared you for your job.	○	○	○	○	○	○
You received clear guidelines and expectations when you started your job.	○	○	○	○	○	○
You were given a team-specific orientation when you started.	○	○	○	○	○	○
Access to the tools and resources to perform your job effectively.	○	○	○	○	○	○
My experience with the CTP has matched my expectations.	○	○	○	○	○	○
Job provides a sense of purpose and fulfillment.	○	○	○	○	○	○
Job responsibilities align with the overall goals and mission of the CTP	○	○	○	○	○	○
Work-life balance - Feeling supported and not overwhelmed with your job.	○	○	○	○	○	○

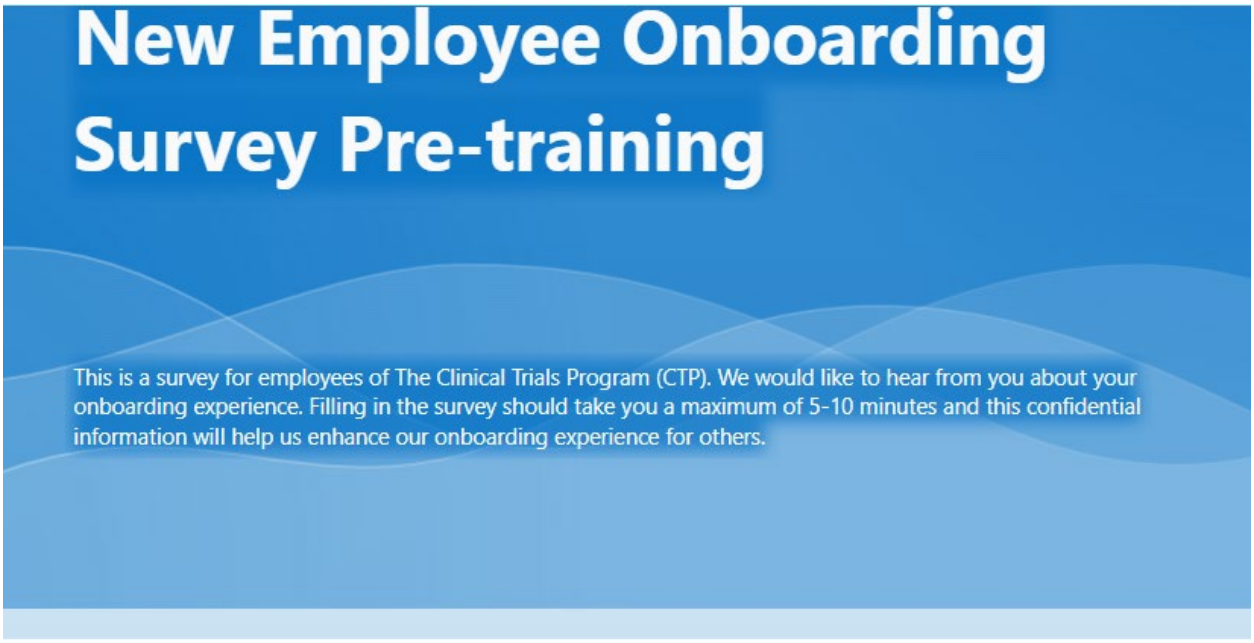
5. I think about looking for a job at another company. (1= extremely unlikely, 10= extremely likely)

1	2	3	4	5	6	7	8	9	10

6. What are three things you wish you had been trained on when you started?

Appendix H

NEO Pre-Training survey



1. **Please rate your experience with the following aspects of your training.**

	Extremely Dissatisfied	Dissatisfied	Neutral	Satisfied	Extremely Satisfied	Not Applicable
I was given a clear understanding of the onboarding process in advance.	◯	◯	◯	◯	◯	◯
I received the materials I needed for onboarding promptly, without having to ask.	◯	◯	◯	◯	◯	◯
I had a clear idea of what to do (and where to go) on my first day.	◯	◯	◯	◯	◯	◯

The team did their best to make me feel welcome ahead of my first day.	◯	◯	◯	◯	◯	◯
You were given a team-specific orientation when you started.	◯	◯	◯	◯	◯	◯
Understanding of the scope and standards of the clinical research nurse.	◯	◯	◯	◯	◯	◯
Understanding of the rules and regulations related to human research.	◯	◯	◯	◯	◯	◯
My experience with The CTP has matched my expectations	◯	◯	◯	◯	◯	◯
Understanding of The CTP's vision and strategy.	◯	◯	◯	◯	◯	◯

2. **What is one thing you would change about your onboarding experience so far?**

Enter your answer

Appendix I

New Employee Survey 30 & 60 Day Check In

New Employee Onboarding Survey 30 & 60 day check in

This is a survey for employees of The Clinical Trials Program (CTP). We would like to hear from you about your onboarding experience. Filling in the survey should take you a maximum of 5-10 minutes and this confidential information will help us enhance our onboarding experience for others.

1. Please rate your experience with the following aspects of your training.

	Extremely Dissastisfied	Dissatisfied	Neutral	Satisfied	Extremely Satisfied	Not Applicable
Team-specific orientation from your manager	◯	◯	◯	◯	◯	◯
Clear understanding of your role and responsibilities.	◯	◯	◯	◯	◯	◯
Clear path for next steps in your role.	◯	◯	◯	◯	◯	◯
Sense of camaraderie and teamwork within your department.	◯	◯	◯	◯	◯	◯
Understanding of the scope and standards of the clinical research nurse	◯	◯	◯	◯	◯	◯
Understanding of the rules and regulations related to human research.	◯	◯	◯	◯	◯	◯

Understanding of the rules and regulations related to human research.	◯	◯	◯	◯	◯	◯
Understanding of how nursing ethics is applied to the CTRN role.	◯	◯	◯	◯	◯	◯
Adequate support in managing stress and maintaining mental well-being.	◯	◯	◯	◯	◯	◯
Your first 30/60 days of training met your expectations.	◯	◯	◯	◯	◯	◯
Training answered all your questions or concerns.	◯	◯	◯	◯	◯	◯

2. What is one thing you would change about your training experience so far?

Enter your answer

Appendix J

NEO Post-Training Survey

New Employee Onboarding Survey

Post Training

This is a survey for employees of The Clinical Trials Program (CTP). We would like to hear from you about your onboarding experience. Filling in the survey should take you a maximum of 5-10 minutes and this confidential information will help us enhance our onboarding experience for others.

1. **What is your Job Title?** **CTRN ☐** **CRC ☐**

2. **Please rate your experience with the following aspects of your training.**

Scale	Extremely Dissatisfied	Dissatisfied	Neutral	Satisfied	Extremely Satisfied	Not Applicable
Feeling confident in your role.	☐	☐	☐	☐	☐	☐
Clear understanding of your role and responsibilities of job and expectations.	☐	☐	☐	☐	☐	☐

Comfortable describing your role to others.	☐	☐	☐	☐	☐	☐
I feel comfortable connecting and collaborating with my team.	☐	☐	☐	☐	☐	☐
Understanding of the scope and standards of the clinical research nurse.	☐	☐	☐	☐	☐	☐
Understanding of the rules and regulations related to human research.	☐	☐	☐	☐	☐	☐
Understanding of how nursing ethics is applied to the CTRN role.	☐	☐	☐	☐	☐	☐
Understanding of The CTP goals.	☐	☐	☐	☐	☐	☐
Regular useful feedback from my manager about my	☐	☐	☐	☐	☐	☐
The training I received prepared me for my job.	☐	☐	☐	☐	☐	☐

3. If you could describe your onboarding in one word, what would that word be?

4. Any information gaps?
5. What's one thing we could have done differently to improve your onboarding experience?

Appendix K

NEO checklist

30-60-90 Day NEO Checklist

CTP New Employee Onboarding

Required Activity	Date Completed
Complete by Day 30	
Welcome and Introduction to Clinical Research Nursing	
CRN scope and SOP book read pg. 1-8 Introduction	
Values: Providing the most effective and safe medical and device therapies for KP members Performing trials and observational studies that develop evidence-based medicine Establishing KPNC as the program-wide leader in clinical trials Establishing KPNC and KP overall as clinical trial leaders nationally Establishing "best in class" infrastructure, operations, and regulatory compliance	
The Clinical Trials Program - Bi-Fold Brochure - About The CTP.pdf - User View (kp.org)	
*Complete CTP NEO *onboarding survey* *https://forms.office.com/Pages/ResponsePage.aspx?id=xHuKPzfjpUeg_A1RLA4F8dAIXu73STpNvY-mO2pt4oFUMTNGRDQ0WDU0TDZGV1U3VU81QUtZSDM0Ry4u*	
Pleasanton Security will send an email to pick up badge and take picture.	
Complete set up laptop including VPN connection, phone, if applicable activate NUID	
Attend Clinical Trials Program Orientation Date Scheduled: _____	
Attend team orientation Date Scheduled: _____	
Attend building tour	
Confirm access to HealthConnect, Microsoft teams	
Timecard training	
The Clinical Trials Program - Home (kp.org) Save to your web favorites	
Clinical Trials Program - Kaiser Permanente Division of Research	
Homepage - Kaiser Permanente Division of Research	
About DOR - Kaiser Permanente Division of Research	
Complete telecommuter agreement-if applicable	
History - Kaiser Permanente Division of Research **watch video**	
Learnings	

Courses and Trainings (kp.org) This is The CTP website under development. Most learners below should be here also.	
HealthStream:	
https://www.healthstream.com/HSAPP/	
APEX Innovations: NIH Stroke Scale Training and 1-Year Certification (free course)	
NHCPS Handbook Course - BLS: Basic Life Support**Only if needed**	
KP learn:	
Data Loss Prevention	
DOT shipping Category A	
DOT general awareness	
NCAL annual review	
Equal access and Effective communication at KP	
Annual ethics & compliance	
COVID 19 training	
Slip, trip, and fall prevention	
BE FAST Stroke training (KP Learn Class ID 0000948413)	
Safe Patient Handling Ambulatory (Clinical) 2024 (KP Learn Class ID 0001076886)	
2024 Preventing Health Care Acquired Infections (KP Learn Class ID 0001089900)	
OSHA Clinical Safety Training for CA – Hospitals and MOBs 2024 (KP Learn Class ID: 0001092749)	
Prevention of workplace violence	
Mental Health Training for Employees	
Preventing harassment in the workplace for employees	
NCAL Division of Research: Regression Modeling	Too hard higher level
Safe Handling of Hazardous Drugs for Nursing 2024 (LVN/RN only) (KP Learn Class ID 0001076872)	
Diversity Science:	
Creating identity safe teams by understanding & preventing identity threat	
Overcoming unconscious bias in the workplace	

Citi:	
Hipaa 101	
Human subjects	
GCP	
Research Integrity	
Conflict of Interest for Research the is not Federally Funded	
Basic Refresher Course – Human Subjects Protection	
Level 1 – Drug	
DOT	
Courtesy lab draw:	
6. Standing Order Overview for Staff and Managers (complete if applicable) - Standing Order Overview for Staff and Managers-20231130_132018-Meeting Recording.mp4	
Clinical Trial Design - Clinical Trial Design - CCR Wiki (cancer.gov) Three learnings Part 1-3	
Responsibilities of the Research Team - Responsibilities of the Research Team - CCR Wiki (cancer.gov) Three learnings Part 1-3	
Applications	
Verily-CTMS verily university	
Appian RBM-resolve query	
KP healthconnect Cadance-visit schedulesp-cloud.kp.org/sites/TheClinicalTrialsProgram/The Clinical Trials Program Repository/Forms/AllItems.aspx?id=%2Fsites%2FTheClinicalTrialsProgram%2FThe Clinical Trials Program Repository%2FManuals and Work Instructions%2FTraining Support Documents%2FCadence %28KPHC%29%2FKPLearn Cadence Training%2Epdf&parent=%2Fsites%2FTheClinicalTrialsProgram%2FThe Clinical Trials Program Repository%2FManuals and Work Instructions%2FTraining Support Documents%2FCadence %28KPHC%29	
CTP ebinder, CTMS, Appian training: https://sp-cloud.kp.org/sites/TheClinicalTrialsProgram/SitePages/Courses-and-Trainings.aspx#browse-our-course-catalogue See under Get Access on webpage	
Complete conflict of interest form	
Standard Operating Procedures (kp.org) Current SOP landing page for The CTP	
Read the Belmont Report | HHS.gov	
Read CRN scope and SOP pg. 26-31 Nursing ethics	

APJON-7-237.pdf (nih.gov) The oncology CRN past, present and future	
Read CRN scope and SOP pg. 12-20, 41-42	
Read CRN scope and SOP pg. 45-84 standards of practice for CRN	
Develop or revise existing CV (resume)	
**30-day NEO survey*	
Completed by Day 60	
Informed Consent	
Read CRN scope and SOP pg. 23-24	
Adobe sign training	
New florence econsent training	
Informed Consent - Informed Consent - CCR Wiki (cancer.gov) Four trainings Part 1-4	
Source Documentation	
Ready CRN scope and SOP pg. 37-38, HER, privacy, big data	
Florence training	
Smartphrase training:	
SmartPhrase Expectations for Compliance.pdf	
https://sp-cloud.kp.org/sites/TheClinicalTrialsProgram/_layouts/15/viewer.aspx?sourcedoc={5498a416-9b04-4f6f-ad77-5c7eef7a9150}	
Courses and Trainings (kp.org) See under Healthconnect courses: CTP smarthphrases, Cadence, and HC template	
Watch 'CTP SmartPhrases: Compliantly Document Clinical Trial Encounters' | Microsoft Stream (Classic)	
Documentation and Document Management - Documentation and Document Management - CCR Wiki (cancer.gov) Two Trainings Part 1 & 2	
EDC-imedidata learnings: (must have imedidata access)	
Medidata classic RAVE EDC essentials for read only users	
Medidata classic rave edc essentials for CRC	
Rave reporter	

Getting started in imedidata	
Medidata imaging intro	
Site specifics image	
Study workflow document	
*60-day NEO survey	
Complete by Day 90	
Adverse events	
Adverse Events - Adverse Events - CCR Wiki (cancer.gov) Four trainings Part 1-4	
Kaiser Permanente Nursing: Nursing Pathways: Professional Development (kpnursing.org) RN information for you	
Shadow SIV-mentor	
Post training NEO survey	
kpLIBRARIES HOME - kpLibraries Home Page - LibGuides at kpLibraries For your information	

By signing this you are attesting that to completing the training provided above.

Name	Role	Electronic Signature	Date
	Manager		
	Employee		

Appendix L

Clinical Trials Standard Operational Workflow

Clinical Trial Study Processes

Name	Role with The CTP	Electronic Signature	Date
	Domain Lead		

Table of Contents

Appendix L con't

Clinical Trials Standard Operational Workflow

Study Preparation for CTRN

The following steps are for nurses to prepare before the site initiation visit (SIV) which is required before the kick off of a new clinical trial study.

- Check IRBnet for documents if they are not received by regulatory specialist (RS).
  - Confirm with RS for approval of documents for study.
  - RS listed on website.
  - Approved documents should be in Florence.
- Print study team list.
- Read IRBnet local context form.
  - Summary of enrollment plan.
- Draft workflow that includes:
  - Purpose
  - Product
  - Pharmacy
  - Lab
  - PI (Principal Investigator) expectations
- Read protocol at least week prior to SIV (Site initial visit):
  - To ensure clarity of workflow:
  - Start with synopsis
  - Any washout periods for prohibited medications, etc.
- Read ICF (Informed Consent Form).
- Get ECRF to start SmartPhrases.
- Contact PI: enrollment group.

Study Initiation Visit (SIV)

The SIV is a meeting that is with the Sponsor to review the study requirements. The following steps are for nurses to prepare before the SIV.

- Once notified by the manager:
  - Schedule the Site Initiation Visit (SIV) with the sponsor.
  - Notify Logistics for kickoff meeting.
- Determine the minimal attendance requirement for the SIV based on the study team composition.
- Ensure relevant personnel, such as the principal investigator (PI), lead study coordinator or nurse, pharmacy staff (if applicable), lab personnel, and regulatory specialist, are present.
- Review from Florence the study protocol and informed consent documents.
- Understand study specifics:
  - Purpose
  - Product type (drug or device)
  - Administration methods
  - Inclusion/Exclusion criteria
  - Visit schedules, and adverse event (AE) reporting procedures.
  - Enrollment Target

Appendix L con't

Clinical Trials Standard Operational Workflow

- Where at with target-get sense of urgency
- DOA (Delegation of Authority) gets quality and sponsor approval with Regulatory specialist cc'd.
  - Upon approval have CRC (Clinical research coordinator) upload and send out for signatures.

During the Study

After the study kick off is completed, the following steps are for nurses to monitor throughout the clincial trial.

- Implement workflow based on the protocol and to ensure participant wellbeing.
  - Considering patient screening methods
  - Medication management
  - AE documentation
  - Schedule of events
- Ensure adherence to IRB:
  - approved procedures
  - patient-facing materials and questionnaires.
- Monitor patient enrollment and study progress.
  - collaborating with the PI and study team as needed
- Document and report AEs accurately, following sponsor and regulatory guidelines.
- Maintain communication with the sponsor, regulatory specialist, and other stakeholders regarding study progress and any issues encountered.

Study Close Out Visit (COV)

The following steps are for nurses to prepare before the COV per notification from the sponsor that the clinical trial is concluding.

- Inform sponsor of last patient visit.
- Coordinate closeout activities, including final patient visits and data collection.
- Schedule closeout visits with the sponsor, ensuring relevant personnel are present. PI, Pharmacist, Regulatory specialist, etc.
  - Confirmation letter will state expected agenda for COV
- Complete required documentation, such as regulatory submissions and study invoices.
- Prepare study materials for submission to the sponsor, including signed recruitment plans and signed delegation logs.
- Address any outstanding tasks or queries from the sponsor or regulatory authorities.
- Notify finance teams of study closure and ensure all financial matters are settled.
- IP/device return or destruction-will receive email from sponsor with instructions.

Appendix L con't

Clinical Trials Standard Operational Workflow

AE/SAE Documentation

The list below are the minimum required steps for documentation of adverse/serious adverse events that potentially occur during a study.

- Check labs
  - Notify PI if out of range.
  - CRC uploads to Florence
- Review chart since last study visit for any medical visits.
- Document chief complaint, start and stop dates, ongoing? What was done for AE, if applicable. See PI note for assessment.
- SAE assessment by PI.
- Ensure sponsor notified by PI of SAE/AE documentation and relatedness. Does it need to be reported to IRB?

Additional Considerations

The list below are potential items that may occur and are the responsibility of a CTRN.

- Attending investigator meetings if required by sponsors.
- Order necessary lab tests, imaging studies, or consultations as per the protocol.
- Maintain communication with regulatory specialists to ensure timely receipt of updated consent forms and other regulatory documents.
- Collaborate with quality assurance or compliance teams to ensure adherence to study protocols and regulatory requirements.
- Participate in training sessions and meetings to discuss study procedures and patient management strategies.

Summary of Updates

Created by:	Arin Urban
Version Number:	1
Summary of Updates:	

Document Approval Overview

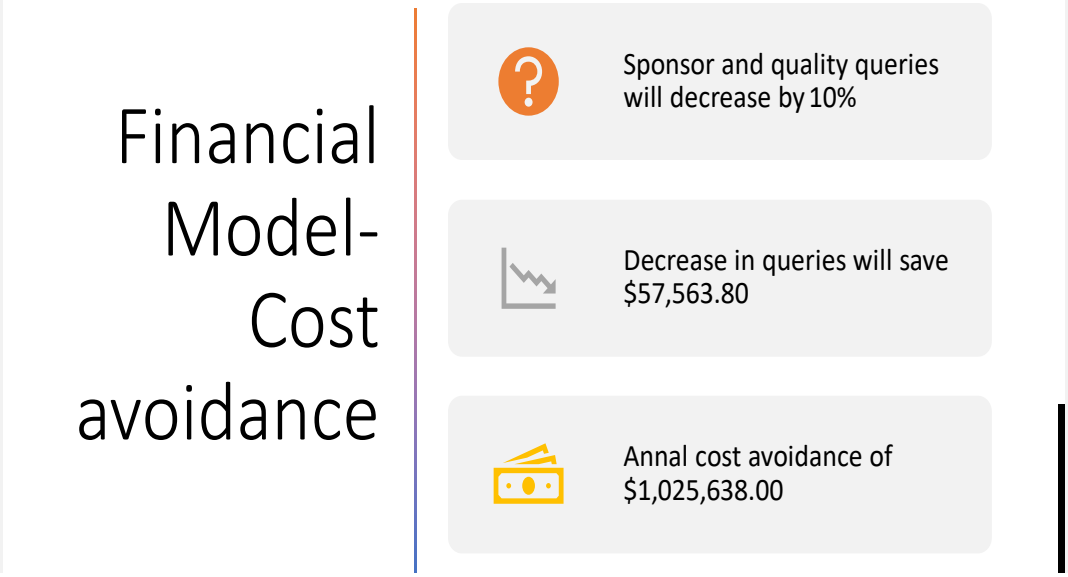
The Clinical Trials Program domain lead(s) listed and signed below, have reviewed, and approve of the content provided in this document.

Name	Role with The CTP	Electronic Signature	Date
	Domain Lead		
	Domain Lead		

Appendix M

Project Budget Analysis

Project Savings (ROI)	
Annual Cost Avoidance	1565563.8
Total Project Cost	147678.12
Project Savings (ROI)	1417885.68



Appendix N

Project Charter

Project Charter: Clinical trial research nurse new employee onboarding 30 60 90-day training checklist

Global Aim: By July 2024, implement standardized training for new employees as clinical trial research nurses in The Clinical Trial Program (CTP).

Specific Aim: Reduce the number of quality queries by 10% from a baseline of 786 and reduce staff turnover by 10 % from 30% to 20%.

Background: Due to the great resignation of 2021(World Economic Forum,2021), eleven of thirteen staff nurses are new, with five of eleven lacking formal training or prior research experience. As a result, data quality is poor, adversely impacting overall efficacy and efficiency within the department. To overcome this challenge, there is a need to develop and implement standardized onboarding and training for new CTP staff that provides a fundamental knowledge standard for research nursing within the American Nurses Association Clinical Research Nursing Scope and Standards of Practice (ANA, 2016). Conversely, if staff are well trained and feel valued in their work, they may be more inclined to stay, thus improving CTP retention.

Sponsors

Sr Learning Consultant	Emma Pinto
Department head	Dr Alan Go
Director	Victor Chen
Manager	Zara Fatima

Goals

To establish baseline knowledge for all CTRNs by implementing a standardized 30 60 90-day training checklist that includes the following:

1. Develop a job satisfaction survey and survey all current CTRN and CRC.
2. Develop a checklist for the training of all new CTRNs that includes an introduction to research and The CTP, competency training, administrative HR onboarding, administrative, clinical research (training videos, job aides, source documentation, data

management, monitor/audits), protocol standard operating procedures, IRB, roles and responsibilities, recruitment, and informed consent.

3. Develop a pre-training survey, 30-day survey, and post-training survey for all new CTRNs.
4. Test of change- training of the 2 CTRNs hired in the last six months.

Measures

Measure	Data Source	Target
Outcome Measures		
% Quality queries	Internal Quality department	10% decrease
% Retention	HR	10% increase
Process Measures		
Checklist training	EB Checklist developed & implemented	
Quality monitoring	Appian	
Train CTRN with new checklist	Microsoft forms	Two new CTRN
Balancing Measures		
Job satisfaction	Microsoft forms	All CTRN & CRC
Retention	Microsoft forms	All CTRN & CRC

Team

CTRN	
Sr Learning consultant	
Manager	
Quality Nurse	
Knowledge management research Assoc	

Appendix O

USF Statement of Determination Checklist

UNIVERSITY OF SAN FRANCISCO | School of Nursing and Health Professions

☒ This project meets the guidelines for an Evidence-based Change in Practice Project as outlined in the Project Checklist (attached). Student may proceed with implementation.

☐ This project involves research with human subjects and must be submitted for IRB approval before project activity can commence.

Comments:

EVIDENCE-BASED CHANGE OF PRACTICE PROJECT CHECKLIST *

Instructions: Answer YES or NO to each of the following statements:

Project Title: CTRN NEO 30 60 90-day checklist	**YES**	**NO**
The aim of the project is to improve the process or delivery of care with established/ accepted standards, or to implement evidence-based change. There is no intention of using the data for research purposes.	x	
The specific aim is to improve performance on a specific service or program and **is a part of usual care**. ALL participants will receive standard of care.	x	
The project is **NOT** designed to follow a research design, e.g., hypothesis testing or group comparison, randomization, control groups, prospective comparison groups, cross-sectional, case control). The project does **NOT** follow a protocol that overrides clinical decision-making.	x	
The project involves implementation of established and tested quality standards and/or systematic monitoring, assessment or evaluation of the organization to ensure that existing quality standards are being met. The project does **NOT** develop paradigms or untested methods or new untested standards.	x	
The project involves implementation of care practices and interventions that are consensus-based or evidence-based. The project does **NOT** seek to test an intervention that is beyond current science and experience.	x	
The project is conducted by staff where the project will take place and involves staff who are working at an agency that has an agreement with USF SONHP.	x	
The project has **NO** funding from federal agencies or research-focused organizations and is not receiving funding for implementation research.	x	
The agency or clinical practice unit agrees that this is a project that will be implemented to improve the process or delivery of care, i.e., **not** a personal research project that is dependent upon the voluntary participation of colleagues, students and/ or patients.	x	
If there is an intent to, or possibility of publishing your work, you and supervising faculty and the agency oversight committee are comfortable with the following statement in your methods section ***"The Research Determination Committee for the Kaiser Permanente Northern California region has determined the project does not meet the regulatory definition of research involving human subjects per 45 CFR 46.102(d)"***	x	

5-17

UNIVERSITY OF SAN FRANCISCO | School of Nursing and Health Professions

ANSWER KEY: If the answer to **ALL** of these items is yes, the project can be considered an Evidence-based activity that does NOT meet the definition of research. **IRB review is not required. Keep a copy of this checklist in your files.** If the answer to ANY of these questions is **NO**, you must submit for IRB approval.

*Adapted with permission of Elizabeth L. Hohmann, MD, Director and Chair, Partners Human Research Committee, Partners Health System, Boston, MA.

STUDENT NAME (Please print):
_Arin Urban, Rn___Clinical Trials Research Nurse_____
Signature of Student:
_____**DATE**_____

SUPERVISING FACULTY MEMBER NAME (Please print): __
_Carla Martin_____
Signature of Supervising Faculty Member
_____**DATE**_____

Preceptor-Sr Learning Consultant
Emma Pinto

_____ **Date**_____

Manager
Zara Fatima

_____ **Date**_____

Regional Director-Div Of Research
Dr. Alan Go

_____ **Date**_____

Appendix P

RDO Non-research Determination Form

KAISER PERMANENTE®

Date: April 16, 2024
Subject: RDO KPNC 24 - 061
Title: Clinical Trial Research Nurse New Employee Onboarding 30 60 90 Day Checklist

Dear Ms. Pinto:

The Research Determination Committee for the Kaiser Permanente Northern California region has reviewed the documents submitted for the above referenced project to be used by Arin Urban for her MSN program. The project does not meet the regulatory definition of research involving human subjects as noted here:

Not Research

The activity does not meet the regulatory definition of research per 45 CFR 46.102(d): Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

This determination is based on the information provided. If the scope or nature of the project changes in a manner that could impact this review, please resubmit for a new determination. The word "research" should not appear in any posters or publications resulting from this project. Further, if publications, presentations or posters are generated from this project the following wording must be used to reference to the project research determination outcome:

"The Research Determination Committee for the Kaiser Permanente Northern California region has determined the project does not meet the regulatory definition of research involving human subjects per 45 CFR 46.102(d)"

You are expected, however, to implement your study or project in a manner congruent with accepted professional standards and ethical guidelines as described in the Belmont Report (http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html).

Additionally, you are responsible for keeping a copy of this determination letter in your project files as it may be necessary to demonstrate that your project was properly reviewed. Provide this approval letter to the Physician in Charge (PIC), your Area Manager, and Chief of Service, to determine whether additional approvals are needed.

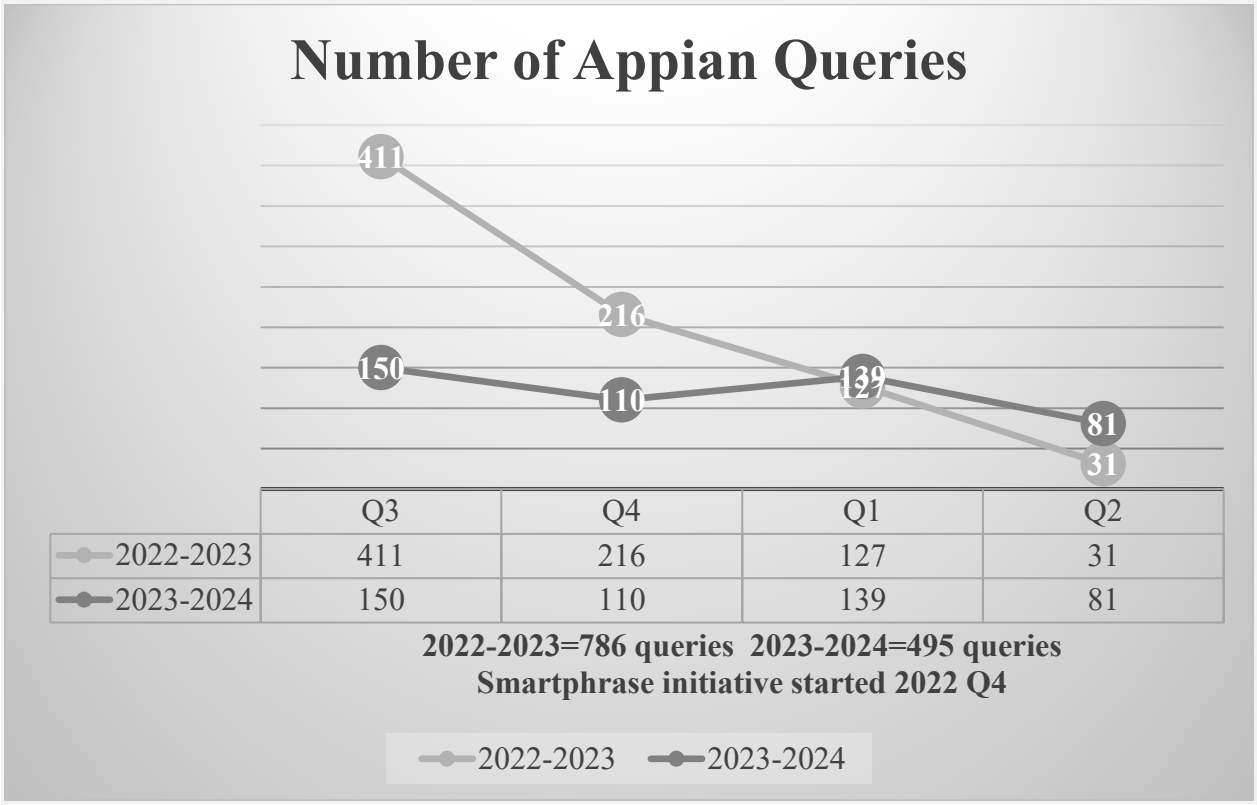
Finally, all manuscripts/case series/case studies must receive written approval prior to submission to a journal or book. The Principal Investigator (PI) or first author (if different) must request their PIC[1], or the Division of Research (DOR) Director[2], or the Research & Innovation Academy (RIA)[3] or an equivalent level leader[4] review and provide written approval for publication submission. The PI is responsible for retaining a copy of the approval.

Sincerely,

The Research Determination Committee
KPNC-RDO@kp.org

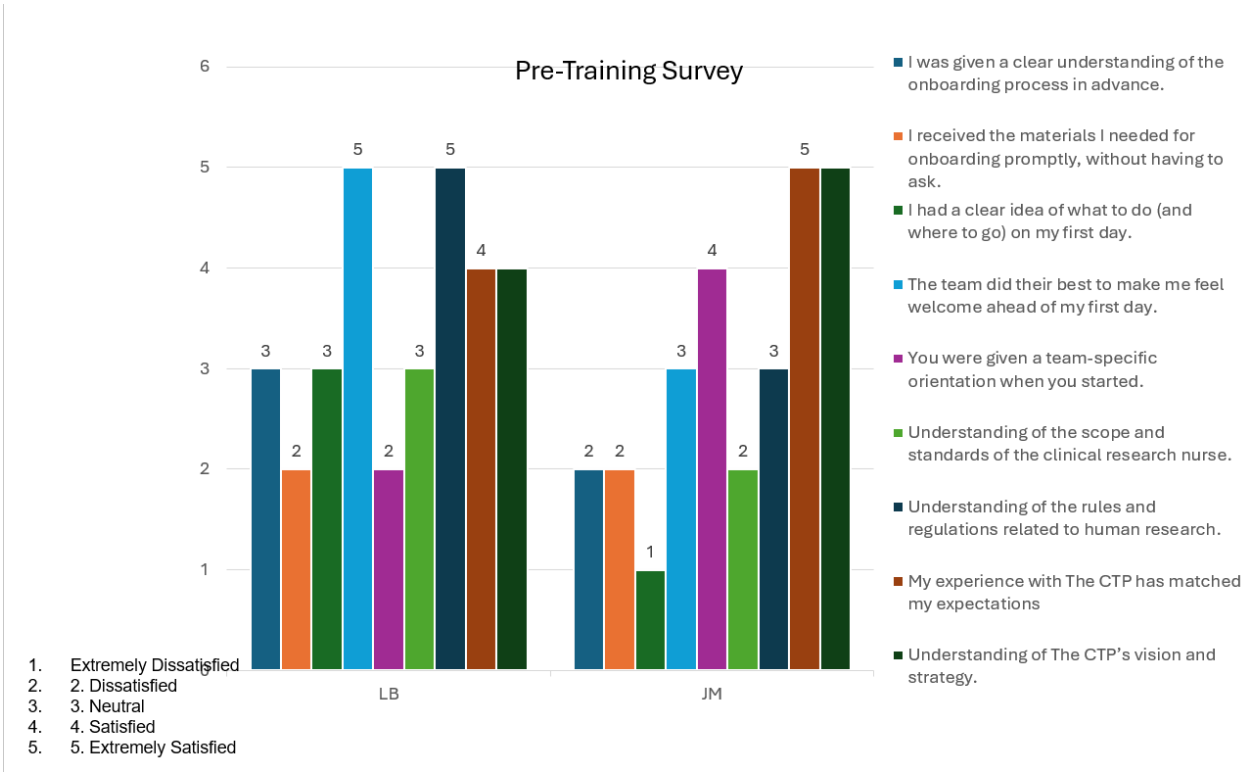
Appendix Q

Quality Queries



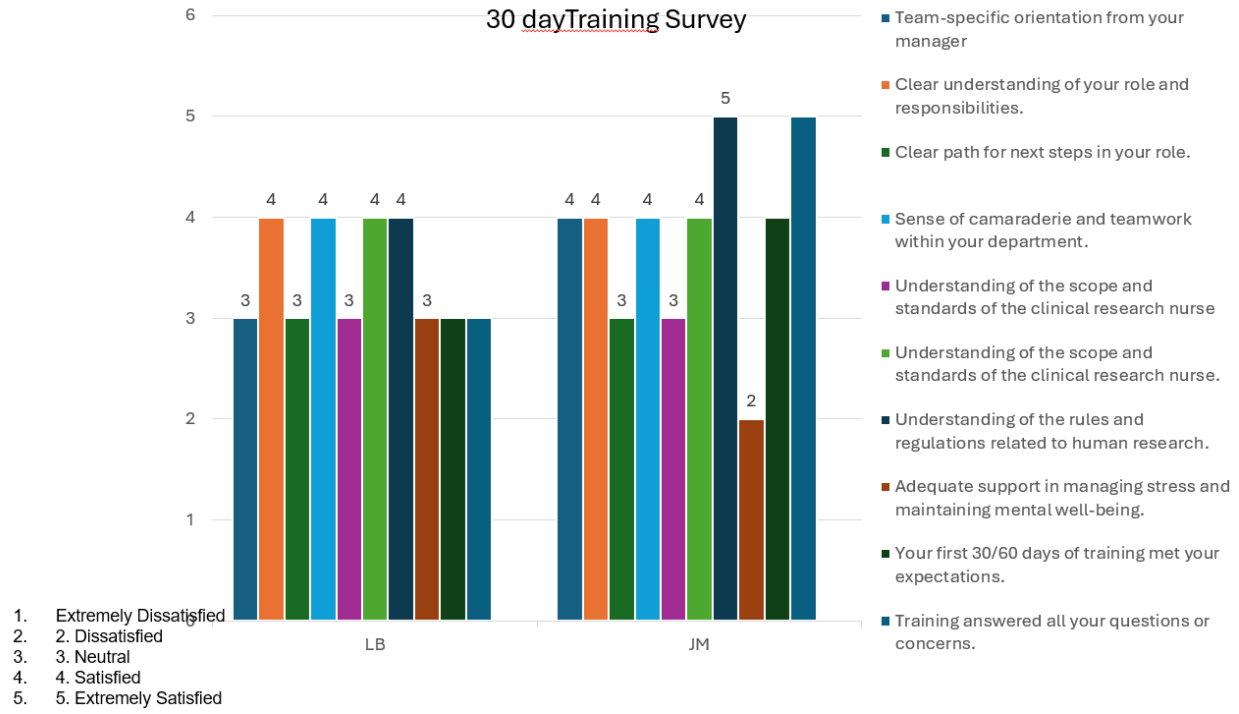
Appendix R

Pre-Training Survey Results (n=2)

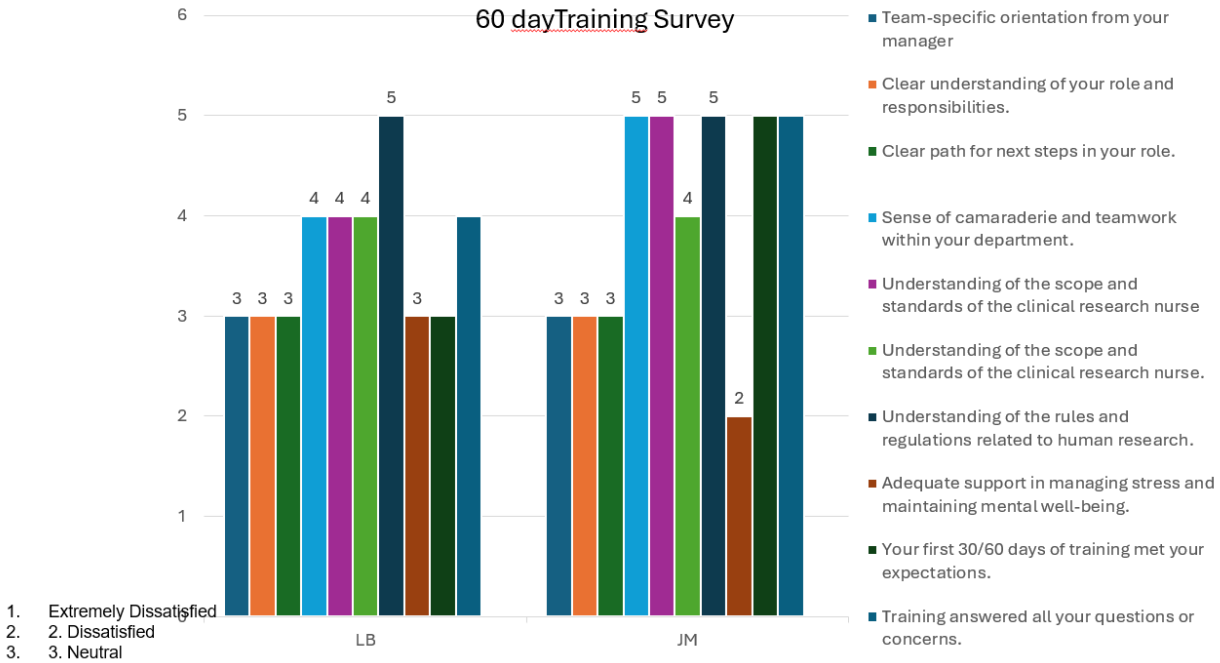


Appendix S

30- & 60-Day Survey Results (n=2)



1. Extremely Dissatisfied
2. 2. Dissatisfied
3. 3. Neutral
4. 4. Satisfied
5. 5. Extremely Satisfied



1. Extremely Dissatisfied
2. 2. Dissatisfied
3. 3. Neutral
4. 4. Satisfied
5. 5. Extremely Satisfied

Appendix T

Post Training Survey Results (n=2)

1. Extremely Dissatisfied
2. 2. Dissatisfied
3. 3. Neutral
4. 4. Satisfied
5. 5. Extremely Satisfied

- "I would like to have a playbook of who is who and what is what for this position"
- "Just having experienced people understand that they are dealing with someone coming from a different specialty is new. Things are very different here; rules are different, and not to make you feel inferior if you don't know how to do something. Also, give out praise when you're working hard. Acknowledgment goes a long way in feeling supported."
- "I would like to see the order of training rearranged. As someone who had never been in research, I think it is important to start with the foundations and history of research, then begin training courses (CITI, for example), and shadow real-life trials."

Appendix U

CTRN Satisfaction Survey Results (n=13)

¤	Your job overall¤	Understanding of your role and responsibilities¤	A well-organized list of training s was provided when you started¤	The training s you received when you started prepared you for your job¤	You received clear guidelines and expectations when you started your job¤	You were given a team-specific orientation when you started¤	Access to the tools and resources to perform your job effectively¤	My experience with the CTP has matched my expectations¤	Job provides a sense of purpose and fulfillment¤	Job responsibilities align with the overall goals and mission of the CTP¤	Work-life balance -- Feeling supported and not overwhelmed with your job¤
	d¤										
13¤	Satisfied¤	Satisfied¤	Dissatisfied¤	Neutral¤	Dissatisfied¤	Dissatisfied¤	Neutral¤	Satisfied¤	Satisfied¤	Satisfied¤	Satisfied¤
14¤	Satisfied¤	Satisfied¤	Satisfied¤	Satisfied¤	Satisfied¤	Satisfied¤	Satisfied¤	Satisfied¤	Satisfied¤	Satisfied¤	Extremely Satisfied¤
15¤	Satisfied¤	Extremely Satisfied¤	Satisfied¤	Satisfied¤	Satisfied¤	Satisfied¤	Satisfied¤	Satisfied¤	Extremely Satisfied¤	Extremely Satisfied¤	Satisfied¤
16¤	Extremely Satisfied¤	Extremely Satisfied¤	Dissatisfied¤	Satisfied¤	Satisfied¤	Not Applicable¤	Extremely Satisfied¤	Extremely Satisfied¤	Extremely Satisfied¤	Extremely Satisfied¤	Satisfied¤
17¤	Satisfied¤	Satisfied¤	Dissatisfied¤	Dissatisfied¤	Dissatisfied¤	Dissatisfied¤	Satisfied¤	Neutral¤	Extremely Satisfied¤	Extremely Satisfied¤	Extremely Satisfied¤
18¤	Extremely Satisfied¤	Neutral¤	Not Applicable¤	Not Applicable¤	Not Applicable¤	Not Applicable¤	Satisfied¤	Not Applicable¤	Extremely Satisfied¤	Neutral¤	Satisfied¤
19¤	Extremely Satisfied¤	Extremely Satisfied¤	Satisfied¤	Satisfied¤	Satisfied¤	Satisfied¤	Satisfied¤	Satisfied¤	Extremely Satisfied¤	Extremely Satisfied¤	Satisfied¤

This table summarizes the satisfaction levels across various aspects of the job. Each row represents a different individual's responses.¶

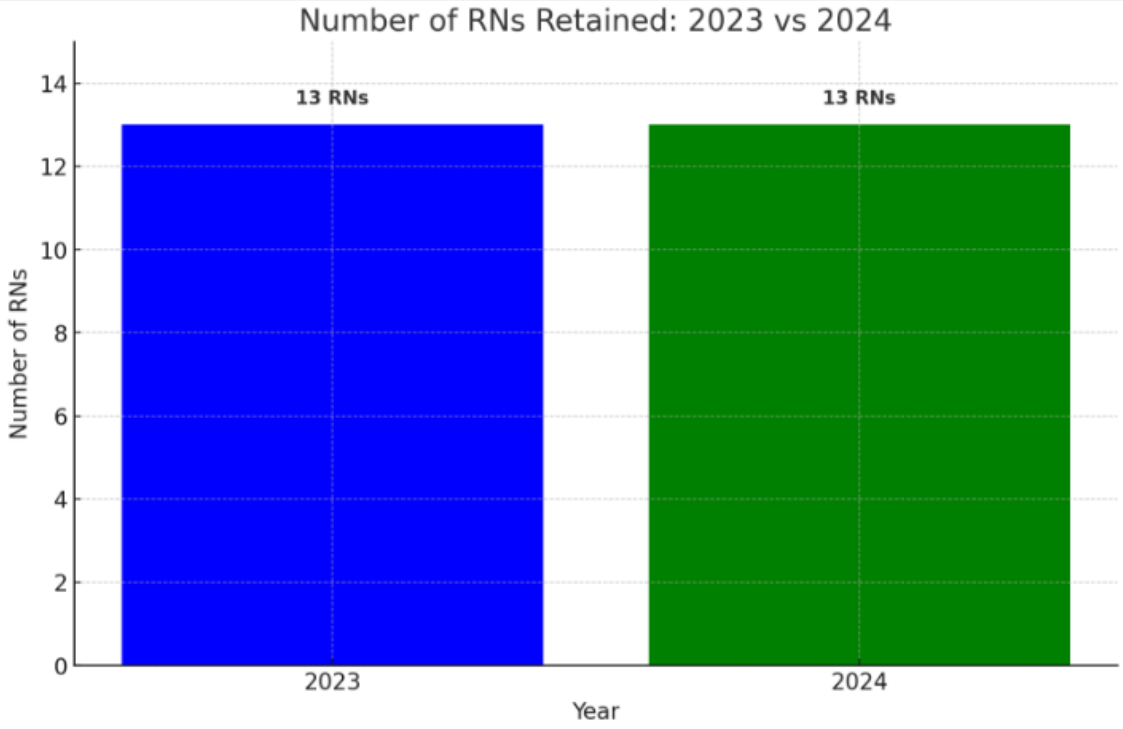
¤	Your job overall¤	Understanding of your role and responsibilities¤	A well-organized list of trainings was provided when you started¤	The trainings you received when you started prepared you for your job¤	You received clear guidelines and expectations when you started your job¤	You were given a team-specific orientation when you started¤	Access to the tools and resources to perform your job effectively¤	My experience with the CTP has matched my expectations¤	Job provides a sense of purpose and fulfillment¤	Job responsibilities align with the overall goals and mission of the CTP¤	Work-life balance - Feeling supported and not overwhelmed with your job¤
1¤	Extremely Satisfied¤	Satisfied¤	Satisfied¤	Satisfied¤	Satisfied¤	Satisfied¤	Satisfied¤	Satisfied¤	Extremely Satisfied¤	Extremely Satisfied¤	Extremely Satisfied¤
2¤	Extremely Satisfied¤	Satisfied¤	Extremely Dissatisfied¤	Extremely Dissatisfied¤	Extremely Dissatisfied¤	Extremely Dissatisfied¤	Satisfied¤	Neutral¤	Satisfied¤	Neutral¤	Extremely Satisfied¤
3¤	Satisfied¤	Satisfied¤	Dissatisfied¤	Satisfied¤	Dissatisfied¤	Dissatisfied¤	Dissatisfied¤	Neutral¤	Satisfied¤	Satisfied¤	Neutral¤
4¤	Satisfied¤	Satisfied¤	Dissatisfied¤	Dissatisfied¤	Satisfied¤	Extremely Dissatisfied¤	Neutral¤	Neutral¤	Satisfied¤	Satisfied¤	Neutral¤
5¤	Satisfied¤	Satisfied¤	Neutral¤	Satisfied¤	Satisfied¤	Extremely Satisfied¤	Satisfied¤	Satisfied¤	Extremely Satisfied¤	Extremely Satisfied¤	Satisfied¤
6¤	Extremely Satisfied¤	Satisfied¤	Satisfied¤	Neutral¤	Neutral¤	Extremely Dissatisfied¤	Neutral¤	Extremely Satisfied¤	Extremely Satisfied¤	Extremely Satisfied¤	Extremely Satisfied¤
7¤	Satisfied¤	Satisfied¤	Extremely Satisfied¤	Extremely Satisfied¤	Satisfied¤	Extremely Satisfied¤	Satisfied¤	Satisfied¤	Neutral¤	Extremely Satisfied¤	Dissatisfied¤
8¤	Satisfied¤	Neutral¤	Dissatisfied¤	Dissatisfied¤	Neutral¤	Satisfied¤	Satisfied¤	Neutral¤	Satisfied¤	Extremely Satisfied¤	Extremely Satisfied¤
9¤	Extremely Satisfied¤	Satisfied¤	Satisfied¤	Neutral¤	Neutral¤	Neutral¤	Satisfied¤	Neutral¤	Extremely Satisfied¤	Extremely Satisfied¤	Extremely Satisfied¤
10¤	Satisfied¤	Satisfied¤	Dissatisfied¤	Neutral¤	Dissatisfied¤	Dissatisfied¤	Dissatisfied¤	Neutral¤	Dissatisfied¤	Neutral¤	Dissatisfied¤
11¤	Extremely Satisfied¤	Extremely Satisfied¤	Satisfied¤	Extremely Satisfied¤	Extremely Satisfied¤	Extremely Satisfied¤	Satisfied¤	Extremely Satisfied¤	Extremely Satisfied¤	Extremely Satisfied¤	Extremely Satisfied¤
12¤	Extremely Satisfie	Satisfied¤	Satisfied¤	Dissatisfied¤	Dissatisfied¤	Neutral¤	Dissatisfied¤	Neutral¤	¤	Extremely Satisfied¤	Dissatisfied¤

Survey Comment summary

Properly conducting consenting.
Getting ready for Site initiation visit (SIV)
What are queries and how to resolve
Roles and responsibilities
Improving orientation and training
Workflow wanted
Management communication wanted

Appendix V

Retention Data



Here is the chart showing that the number of RNs retained remained the same at 13 in both 2023 and 2024.