ASCO® Research Community Forum

TOOLKIT OF RESOURCES

The Business of Clinical Trials

Optimizing Clinical Trial Sites and Implementing Best Practices

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OVERVIEW

This Toolkit was developed as part of an initiative led by the American Society of Clinical Oncology's Research Community Forum (ASCO RCF), which provides tools and resources to assist oncology research programs with conducting and managing clinical trials. It contains numerous links to helpful references as well as templates, checklists, and forms to assist research sites with clinical trial operations and building an effective research program. This Toolkit was initially prepared for a workshop at the 2018 ASCO Research Community Forum Annual Meeting, *The Business of Clinical Trials: Optimizing Clinical Trial Sites and Implementing Best Practices*.

The references and resources are not exhaustive and decisions to include resources were based on the contributors' own go-to resources, consultation with colleagues, and an environmental scan of available resources. Resources from commercial entities or that are made available for profit are generally excluded. The references are not necessarily endorsed by ASCO; they are listed based on the discretion and expertise of the contributors noted in the acknowledgements. If you have suggestions for additional resources for inclusion, please email them to researchcommunityforum@asco.org.

ACKNOWLEDGEMENTS

There are several important contributors to this Toolkit: Kandie Dempsey, Nancy Burns, Marge Good, and Kelly Willenberg all contributed both expertise and content, including resources and key references. Their contributions helped to build the section and resources on *Research Program Operations: Running an Effective Oncology Clinical Trial Program.* Jamie Harper and Philip Butera also provided references and templates. Some of the resources are adapted, with permission, from materials they have developed to assist them with research program operations.

Dr. David Waterhouse and Dr. Daniel Flora contributed references to the section on *Optimizing Clinical Trial Sites: Building an Effective Research Program*.

Patricia Hurley, Courtney Davis, and Niké Alade, from ASCO's Center for Research and Analytics also assisted with developing the toolkit.

Disclaimer: This Toolkit contains templates and resources that are provided as examples only for research programs to consider as they formulate their own resources.

When citing this Toolkit, or any of its components, please include the following content in the citation:

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ASCO Research Community Forum

OPTIMIZING CLINICAL TRIAL SITES:

Building an Effective Research Program

BUILDING AN EFFECTIVE RESEARCH TEAM

This section of the toolkit provides links to helpful resources for building an effective research program, focusing on the areas of fostering mentorship, creating a culture of research, establishing successful partnerships and affiliations, and stimulating financial and site development growth.

Mentorship

Mentoring is an important component of building an effective research program, benefitting both mentees and mentors. The links below provide guidance on the impact of mentorship and how to get started.

- Henry-Noel N, Bishop M, Gwede CK, et al: Mentorship in medicine and other health professions. Journal of Cancer Education [Epub ahead of print] DOI: 10.1007/s13187-018-1360-6. In this article, the authors describe the development of optimal mentoring relationships, emphasizing the importance of different approaches to mentorship, roles of the mentors and mentees, mentor and mentee benefits, interprofessional mentorships for teams, gender and mentorship, and culture and mentorship.
- Arnold ER: As a new nurse myself, how can I become a mentor to new nurse colleagues? Clinical Journal of Oncology Nursing 22:120, 2018.

Creating a Culture of Research

Creating a culture of research within an organization helps to ensure commitment and buy-in to participation in clinical trials.

- Dimond EP, St Germain D, Nacpil LM, et al: Creating a "culture of research" in a community hospital: Strategies and tools from the National Cancer Institute Community Cancer Centers Program. Clinical Trials 12:246-256, 2015. The National Cancer Institute Community Cancer Centers Program experience provides a relevant model to broadly address creating a culture of research in community hospitals that are increasingly networked via systems and consortiums.
- Alvins AL, Goldberg H: Creating a culture of research. Contemporary Clinical Trials 28:557-562, 2007.

Partnerships

A strong partnership is commonly at the heart of a successful clinical research program. Use the resources below to learn about the benefits and how to establish effective partnerships.

- Communities as Partners in Cancer Clinical Trials: Changing Research, Practice and Policy. Communities as Partners in Cancer Clinical Trials is supported by grant number 1-R13-HS016471 from the Agency for Healthcare Research and Quality (AHRQ), with co-funding from the National Cancer Institute (NCI). This is a copy of their report highlighting the potential impact of the community site and need for improved partnerships.
- NCI's National Clinical Trials Network (NCTN). NCI's National Clinical Trials Network (NCTN) is a collection of organizations and clinicians that coordinates and supports cancer clinical trials at more than 3,000 sites across the United States and Canada. The NCTN provides the infrastructure for NCI-funded treatment, screening, and diagnosis trials to improve the lives of patients with cancer.
- Conway L: Academic-community cancer program affiliations: How to make sure you both benefit. The Advisory Board Company: Oncology Roundtable 2014. This briefing covers five dimensions of affiliations to help you take the informed approach needed to structure a productive, mutually beneficial partnership.

- Welford B: The 12 step checklist for a successful business partnership. Under 30 CEO. The priority and timing for the goals to be achieved by the partnership should be equally satisfactory for both partners. Those of us in the cancer community can learn from our business colleagues.

Finance and Site Development/Growth

Review the links below to learn about return on investment in clinical cancer research, how to develop an investigator site budget, and the basic requirements for starting a research site.

- Fricker J: Study estimates economic returns from UK cancer research. The Lancet Oncology 15:e314, 2014. This study shows that there is a 40% return on investment yearly for each pound spent on clinical cancer research in the UK!
- Developing an investigator site budget for clinical trials. Journal of Oncology Practice 3:94-97, 2007. Article discussed site budget issues and the importance of covering all costs.
- American Society of Clinical Oncology: Basic Requirements for Starting a Research Site. This is an online resource that is updated periodically but can be very helpful as you start and grow your site.

RESEARCH PROGRAM OPERATIONS:

Running an Effective Oncology Clinical Trial Program

BUILDING AN EFFECTIVE RESEARCH TEAM

Clinical trial organizations have many challenges associated with conducting and managing clinical trials. The benefits gained from a solid infrastructure, good lines of authority, and defined roles and responsibility can greatly improve running trials. The variability of such structures across research programs is immense, with some having nurses in roles, while others do not. This portion of the toolkit provides samples of staffing models and position descriptions. You will also find strategies to gauge workload and competencies, and provide training.

Organization Charts

See Appendix A for two sample clinical trial program organization charts: one with a larger executive suite, including the CEO, vice presidents, and medical directors, and another with a more streamlined hierarchy, stemming from the CEO and medical director.

Staffing Models

An effective staffing model is key to ensuring a successful workflow and collaborative work culture. The following resources provide strategies to employ effective project managers and clinical research coordinators, learn the attributes of exemplary research, and foster interdisciplinary team work.

- Larkin ME, Blumenthal K, Richards D, et al: Collaborative staffing model. Applied Clinical Trials 2011.
- Nancarrow SA, Booth A, Ariss S, et al: Ten principles of good interdisciplinary team work. Human Resources for Health 11:1-11, 2013.
- Schultz A: 4 essential skills for the ideal clinical trial project manager. Forte Research News 2017.
- SCORR Marketing & Applied Clinical Trials Talent Survey Report. SCORR Marketing 2017.
- Speicher LA, Fromell G, Avery S, et al: The critical need for academic health centers to assess the training, support, and career development requirements of clinical research coordinators: Recommendations from the clinical and translational science award research coordinator taskforce. Clinical and Translational Science Journal 5:470-475, 2012.
- Baer AR, Zon R, Devine S, et al: Attributes of exemplary research: The clinical research team. Journal of Oncology Practice 7:188-192, 2011.
- Bishop P, Camblos L: The value of empowered CRAs in rare disease studies. Applied Clinical Trials 2017.

Clinical Research Staff Positions

Clinical research staff at a clinical trial site cover a range of roles and responsibilities, and their positions may include Clinical Research Nurse(s), Clinical Research Coordinator(s), Regulatory Coordinator(s), Clinical Research Technician(s), Research Data Manager(s), and Finance and Billing Manager(s). Table 1 describes these clinical trial research staff positions, and Appendix B provides sample job descriptions for each position.

Table 1. Overview of Clinical Trial Research Staff Positions

Research Staff Title	Description	Education and Experience
Clinical Research Nurse	Coordinates study activities throughout the trial to assure integrity and quality is maintained and that the trial is conducted in accordance with federal, state and local regulations, the sponsor protocol and other sponsor requirements, institutional policies and good clinical practice (GCP) guidelines.	Graduate of an approved nursing program, BSN preferred and a minimum of three (3) years of experience in clinical research. (Level I = 0 years, Level II = 1 years, Level III = 5 years, Senior Level = 10 years)
Clinical Research Coordinator	This position provides support and coordination for clinical research studies in order to ensure the efficiency and accuracy of clinical studies through all stages as the study progresses and shows vigilance in participant safety, protocol compliance, and data quality	Bachelor's degree in health science and a minimum of three years clinical and/or research experience. Master's degree replaces two years of needed experience
Regulatory Coordinator	Oversees the day-to-day regulatory management of all types of clinical research protocols. Manage all aspects of study start-up, modification submissions, continuous reporting, and study close out to the Institutional Review Board (IRB) and any relevant regulatory agencies.	Bachelor's degree in Clinical Health Science, Health Administration or related field required. Required time in field previous to employment: Three (3) years of experience in clinical research.
Research Data Manager	Clinical research data specialist ensures that clinical trials data is collected, managed and reported clearly, accurately and securely.	High school diploma or equivalent required. Associate's or bachelor's degree in a science, computer, or business-related field preferred. Two years of related experience. May substitute required experience with completed years of college on a one to one basis.
Finance and Billing Manager	Financial and billing manager of clinical research studies to include maintenance of financial records, invoice processing and management, monthly financial reporting and support for budget negotiations, financial forecasting, monitoring monthly budget expenditures and identifying process improvements.	Bachelor's degree from a four-year college or university. Two years' experience in a financial setting or equivalent combination of education and experience.
Clinical Research Technician	Under direction, assists with the protocol required clinical research activities in accordance with research regulations. Primarily functions to carry out consenting, recruiting and screening of research participants on non-treatment protocols. Duties also include obtaining research data, collecting, processing, and shipping specimens.	High School graduate with one (1) year of clerical or secretarial experience required. Medical assistant and phlebotomy experience preferred. Necessary computer skills. Ability to function independently and as a team member.

Career Ladders

Career ladders are an essential component of staff satisfaction, retention, and professional development. The resources below provide frameworks and models for building a successful career ladder for a clinical trials program. Appendix C also provides a sample career ladder for a clinical research associate.

- Career Excellence Development Program: Career Development Incentive (CED) Program. Integris Jim Thorpe Rehabilitation Hospital 2016.
- The Career Ladder Mapping Project. Shirley Ware Education Center 2002.
- Children's National Health System Genetic Counselor Career Ladder (Table 1) - Kofman L, Seprish MB, Summar M: Climbing the ladder: Experience with developing a large group genetic counselor career ladder at Children's National Health System. Journal of Genetic Counseling 25:644-648, 2016.
- Nursing at the NIH Clinical Center Career Ladder. NIH Clinical Center 2017.
- Framework for Career Ladder Program (Table 1) - Ko YK, Yu S: Clinical ladder program implementation: A project guide. Journal of Nursing Administration 44:612-616, 2014.
- Career Ladder Point System and Associated Activities (Table 1) Warman G, Williams F, Herrero A, et al: The design and redesign of a clinical ladder program: Thinking big and overcoming challenges. Journal for Nurses in Professional Development 32:E1-E7, 2016.
- Advancing from within: The value of clinical ladders. American Association for Respiratory Care (AARC).
- Andrew N: Clinical imprinting: The impact of early clinical learning on career long professional development in nursing. Nurse Education in Practice 13:161-164, 2013.
- Smailes P, Bookless H, Blumenauer C: Clinical research nurse career advancement using clinical ladder programs. Clinical Researcher 10.14524/CR-17-0038.
- Smith W, Salenius S, Cobb C, et al: A survey of clinical research coordinators in the cooperative group setting of the American College of Radiology Imaging Network (ACRIN). Academic Radiology 17:1449-1454, 2010.
- Warman G, Williams F, Herrero A, et al: The design and redesign of a clinical ladder program: Thinking big and overcoming challenges. Journal for Nurses in Professional Development 32:E1-E7, 2016.
- Keenan C: Struggling to keep entry-level staff engaged? Try a performance-based career ladder. The Advisory Board Company: Care Transformation Center Blog 2017.

GCP Best Practices

Good Clinical Practice (GCP) is an international standard for designing, conducting, monitoring, measuring performance, auditing, recording, analyzing, and reporting of clinical trials. The resources below will help you ensure credible and accurate data and results and protection for trial subjects.

- Clinical Trials Transformation Initiative (CTTI) Recommendations. Arango J, Chuck T, Ellenberg S, et al: Good clinical practice training: Identifying key elements and strategies for increasing training efficiency. Therapeutic Innovation and Regulatory Science 10.1177/2168479016635220.
- TransCelerate Recommendations. Site qualification and training. TransCelerate BioPharma, Inc.
- E6(R2) Good Clinical Practice: Integrated Addendum to ICH E6(R1) Guidance for Industry
- ICH Clinical Safety Data Management: Definitions and Standards for Expedited Reporting E2A. 1994.
- ICH Harmonised Tripartite Guideline General Considerations for Clinical TRIALS E8. 1997.

Training, Core Competencies, and Performance

Once the right staff is place, they must receive the appropriate onboarding and continued training, as well as understand the core competencies of their role and how they're expected to perform, to ensure the success of a quality clinical research program. The resources listed below provide helpful guidance on equipping your team for long-term success, and Appendix D details a research nurse coordinator training and orientation tool to help staff understand good clinical practice and the conduct of research.

- Training Log Examples (Figures 2 & 3): Baer AR, Zon R, Devine S, et al: Attributes of exemplary research: The clinical research team. Journal of Oncology Practice 7:188-192, 2011.
- 2016 Oncology Clinical Trials Nurse Competencies. Oncology Nursing Society 2016.
- Harmonized Core Competency Framework. Joint Task Force for Clinical Trial Competency 2014.
- Applied Clinical Trials Editors. Top 3 skills for clinical trial project managers. Applied Clinical Trials 2014.
- Performance Review Tool – Appendix E provides a competency and performance review tool, which includes measurements used as a rating for expectations for the research team.
- American Nurses Association (ANA), International Association of Clinical Research Nurses (IACRN): Clinical research nursing: Scope and standards of practice. American Nurses Association 2016.

Retention and Workload Distribution

In order to run a successful clinical research program, you must determine the workload that staff members can manage without burning out and understand how to keep them engaged and inspired. These resources will help you understand clinical research talent trends, assess appropriate workloads, and identify strategies to retain high-performing staff.

- American Society of Clinical Oncology: Clinical Trial Workload Assessment Tool. 2014.
- Good MJ, Hurley P, Woo KM, et al: Assessing clinical trial-associated workload in community-based research programs using the ASCO Clinical Trial Workload Assessment Tool. Journal of Oncology Practice 12:e536-547, 2016.
- Aarons GA, Sommerfeld DH, Hecht DB, et al: The impact of evidence-based practice implementation and fidelity monitoring on staff turnover: Evidence for a protective effect. Journal of Consulting and Clinical Psychology 77:270-280, 2009.
- Ford E, Jenkins V, Fallowfield L, et al: Clinicians' attitudes towards clinical trials of cancer therapy. British Journal of Cancer 104:1535–1543, 2011.
- Henderson L: Salary and satisfaction. Applied Clinical Trials 26, 2017.
- Henderson L: Catch (& keep) a rising star: Clinical research talent trends. Applied Clinical Trials 27, 2018.
- Katzenbach JR, Smith DK: The discipline of teams. Harvard Business School Publishing Corporation 71:111-120, 2013.
- Kee AN: Investigator responsibilities for clinical research studies: Proper staffing can ensure an investigator is compliant. Medical Practice Management 26:245-247, 2011.

CLINICAL TRIAL OPERATIONS

Effective clinical trial operations involve several fundamental elements, including management and tracking systems, insurance coverage analyses, quality assurance, and optimization of a clinical trial portfolio. This section of the toolkit aims to provide insightful resources to help you and your team excel in each area of clinical trial operation.

Insurance Coverage of Clinical Trials

The ASCO resources listed below will help you prepare the proper coverage in your clinical research program and overcome billing compliance burden.

- The ASCO Clinical Trial Insurance Coverage Analysis Toolkit helps research sites conduct coverage analyses, deal with coverage denials, and navigate the appeals process. The toolkit is available for free by emailing researchcommunityforum@asco.org.
- Szczepanek CM, Hurley P, Good MJ, et al: Feasibility of a centralized clinical trials coverage analysis: A joint initiative of the American Society of Clinical Oncology and the National Cancer Institute**.** Journal of Oncology Practice 13:395-400, 2017.
- Morillo A: Understanding Medicare coverage analysis for clinical trials. Becker's Hospital CFO Report 2012.
- Meade R, Willenberg K, Roach MC: Medicare coverage for cancer research. Journal of Clinical Research Best Practices 6, 2010.
- Willenberg KM: Managing clinical trials-frustration or bliss? The Journal of Oncology Management 13:24-26, 2004.

Clinical Trial Management Systems

Appendix F provides a Clinical Trial Management System (CTMS) checklist, which will aid your team in reviewing your needs for a CTMS. In selecting and purchasing a CTMS, a review of other IT systems and functionality will help to enhance capability once implemented.

Tracking Systems for Management Clinical Trials

Upon request, you can access three invaluable tools to help track data management, research lab specimens, and new patient screening assignments.

- Data Management Tracker – This sample tool helps staff track and prioritize key data milestones for every subject. It has overdue data flags which are automated within the tool to ensure the team will meet data timeliness requirements. To request a copy, contact Nancy.Burns2@unchealth.unc.edu.
- Research Lab Specimen Tracking – This tracking tool can be used by the lab and clinical research team to track research biospecimens. Research sample collection, processing, storage, and shipment are documented in this tool. To request a copy, contact Nancy.Burns2@unchealth.unc.edu.
- Screening Assignments – This screening assignments tool and patient screening log tool enable a team to have clarity on new patient screening assignments (performed daily). To request a copy, contact Nancy.Burns2@unchealth.unc.edu.

Quality Assurance

Appendix G provides a checklist tool to perform a quality assurance audit.

Qualifying Clinical Trial Sites

Several prior and ongoing initiatives seek to establish and harmonize clinical trial site standards, with some examples noted below. The ASCO Research Community Forum has a Task Force that is currently exploring ways to bring stakeholders together to establish multi-stakeholder consensus and buy-in to use common standards as a means to reduce administrative burden on clinical trials sites and expedite clinical trial accrual.

- Zon R, Meropol NJ, Catalano RB, et al: American Society of Clinical Oncology statement on minimum standards and exemplary attributes of clinical trial sites. Journal of Clinical Oncology 26:2562-2567, 2008.
- ASCO Research Program Quality Assessment Tool – Manual, including a checklist and templates is available for free by emailing researchcommunityforum@asco.org.
- Dimond EP, Zon RT, Weiner BJ, et al: Clinical trial assessment of infrastructure matrix tool to improve the quality of research conduct in the community. Journal of Oncology Practice 12:63-64, e23-35, 2015.
- Johnston SC, Austin CP, Lewis-Hall F: Voluntary site accreditation — Improving the execution of multicenter clinical trials. The New England Journal of Medicine 377:1414-1415, 2017.
- Johnston SC, Lewis-Hall F, Bajpai A, et al: It's time to harmonize clinical trial site standards. National Academy of Medicine 10.31478/201710b.
- Koski G, Kennedy L, Tobin MF, et al: Accreditation of clinical research sites - Moving forward. The New England Journal of Medicine 10.1056/NEJMp1806934.

Strategies to Reduce Administrative and Regulatory Burden

Many existing initiatives are designed to improve clinical trial processes and reduce administrative and regulatory burdens. The following are some examples of ASCO and other resources. This list is not exhaustive.

Addressing Administrative and Regulatory Burden

Cancer clinical trials have become more and more challenging to conduct. Research programs must comply with federal and state legal and regulatory requirements that can be inefficient and costly to implement. In addition, institutions and sponsors often interpret these requirements conservatively and thereby add to the complexity and perceived (but often highly theoretical) risk of conducting clinical trials. ASCO has several past and ongoing initiatives that seek to reduce the administrative and regulatory burden of clinical trials and facilitating clinical trial participation and accrual.

- Vose JM, Levit LA, Hurley P, et al: Addressing administrative and regulatory burden in cancer clinical trials: Summary of a stakeholder survey and workshop hosted by the American Society of Clinical Oncology and the Association of American Cancer Institutes. Journal of Clinical Oncology 34:3796-3802, 2016.
- The ASCO Research Community Forum holds an annual meeting where challenges are addressed and solutions are developed. Learn more about the ASCO Research Community Forum and resources for conducting and managing clinical trials at asco.org/research-community-forum.

Adverse Event Reporting

Monitoring patient safety during clinical trials is critical to protecting patients and the overall clinical research process. However, various issues with the FDA's expedited process for reporting serious adverse events of new investigational drugs are creating system burdens and inefficiencies, which, in turn, can endanger clinical trial

participants. The following resources outline the current safety reporting regulations and provide tools to streamline the process.

- Levit LA, Perez RP, Smith DC, et al: Streamlining adverse events reporting in oncology: An American Society of Clinical Oncology research statement. Journal of Clinical Oncology 36:617-623, 2018
- Project: IND safety reporting. Clinical Trials Transformation Initiative (CTTI)
- Final rule: Investigational new drug safety reporting requirements for human drug and biological products and safety reporting requirements for bioavailability and bioequivalence studies in humans. U.S. Food & Drug Administration 2010

Insurance Coverage of Clinical Trials

The ASCO resources listed below will help you navigate to the proper coverage in your clinical research program and overcome billing compliance burden.

- The ASCO Clinical Trial Insurance Coverage Analysis Toolkit helps research sites conduct coverage analyses, deal with coverage denials, and navigate the appeals process. The toolkit is available for free by emailing researchcommunityforum@asco.org.
- Szczepanek CM, Hurley P, Good MJ, et al: Feasibility of a centralized clinical trials coverage analysis: A joint initiative of the American Society of Clinical Oncology and the National Cancer Institute**.** Journal of Oncology Practice 13:395-400, 2017.

Clinical Trial-Associated Workload

Regularly assessing each staff member's workload can help research programs monitor trends and shifts, justify current staffing and the need to hire additional staff, assist with budget planning, ensure workload balance, and ultimately improve staff satisfaction. However, workload assessment can compete with other important clinical trial management tasks, such as maintaining data quality, complying with protocol, and meeting program accrual goals. Several resources address this topic are noted below.

- American Society of Clinical Oncology: Clinical Trial Workload Assessment Tool. 2014.
- Good MJ, Hurley P, Woo KM, et al: Assessing clinical trial-associated workload in community-based research programs using the ASCO Clinical Trial Workload Assessment Tool. Journal of Oncology Practice 12:e536-e547, 2016.
- Good MJ, Lubejko B, Humphries K, et al. Measuring Clinical Trial–Associated Workload in a Community Clinical Oncology Program. DOI: 10.1200/JOP.2012.000797.
- Smuck B, Bettello P, Berghout K, et al. Ontario Protocol Assessment Level: Clinical Trial Complexity Rating Tool for Workload Planning in Oncology Trials. DOI: 10.1200/JOP.2010.000051.
- Fowler & Thomas. Acuity Rating Tool. *Research Practitioner.* 2003;4(2):64-71.
- NCI Consortia Webinar. Assessing Clinical Trial Associated Workload. January 2018.
- NCI Trial Complexity Elements & Scoring Model. 2009.
- James P, Bebee P, Beekman L, et al. Creating an effort tracking tool to improve therapeutic cancer clinical trials workload management and budgeting. DOI: 10.6004/jnccn.2011.0103
- Kee AN. Investigator responsibilities for clinical research studies: Proper staffing can ensure an investigator is compliant. *J Med Pract Manag.* 2011;26:245-247.

GCP Training

Good Clinical Practice (GCP) is an international standard for designing, conducting, monitoring, measuring performance, auditing, recording, analyzing, and reporting of clinical trials. The resources below will help you ensure credible and accurate data and results and protection for trial subjects.

- Clinical Trials Transformation Initiative (CTTI) Recommendations. Arango J, Chuck T, Ellenberg S, et al: Good clinical practice training: Identifying key elements and strategies for increasing training efficiency. Therapeutic Innovation and Regulatory Science 10.1177/2168479016635220.
- TransCelerate Recommendations. Site qualification and training. TransCelerate BioPharma, Inc.

Contract Negotiations

Negotiating clinical trial contracts and budgets is a routine and important activity for clinical trial sites conducting industry-sponsored research. Although all parties involved share the same goal of initiating trial enrollment, the contract must reflect their collective, and sometimes differing, needs, which can make the negotiation process complex. The following resources below will help you overcome the challenges of contract negotiation.

- Thompson MA, Hurley PA, Faller B, et al: Challenges with research contract negotiations in community-based cancer research. Journal of Oncology Practice 12:e626-e632, 2016.
- CEO Roundtable on Cancer Life Sciences Consortium, NCI-Designated Cancer Centers: Standard Terms of Agreement for Research Trial (START) Clauses. National Cancer Institute (NCI) 2009.
- Clinical and Translational Science Award (CTSA) Institutions: Accelerated Clinical Trial Agreement (ACTA). University Industry Demonstration Partnership (UIDP) 2014.
- First Clinical Research: Model Agreements and Guidelines International (MAGI).

Other Initiatives to Address Administrative and Regulatory Challenges for Sites

ASCO directs many policy and advocacy initiatives in an effort to help advocate for the oncology research community:

- ASCO Advocacy Information for states across the United States
- ASCO Common Rule Summary
- ASCO Right to Try Resources
- Clinical Trials Transformation Initiative (CTTI) – CTTI focuses on identifying and promoting practices that will increase the quality and efficacy of clinical trials.
- TransCelerate BioPharma, Inc. - TransCelerate works to identify, prioritize, design, and facilitate implementation of research and practice related solutions. More information is provided in the meeting materials

Increasing Clinical Trial Awareness and Accrual

Below are several resources to help programs increase clinical trial awareness and accrual, focusing on the various barriers to enrollment, representation of underserved populations, and eligibility criteria, as well as strategies for recruitment and enrollment, resources for engaging patients, and professional organizations supporting researchers and research.

Barriers to Enrolling Patients onto Clinical Trials

Although barriers to enrolling patients onto clinical trials has been the subject of many research studies, the low accrual rate among patients with cancer has changed much. The resources below provide insight on this problem and factors that may be impacting it.

- Vose JM, Chuk MK, Giles F: Challenges in opening and enrolling patients in clinical trials. Am Soc Clin Oncol Ed Book 139-143, 2017
- Unger JM, Cook E, Tai E, et al: The role of clinical trial participation in cancer research: Barriers, evidence, and strategies. Am Soc Clin Oncol Ed Book 185-98, 2016
- Maurer MJ, Ghesquières H, Link BK, et al: Diagnosis-to-treatment interval is an important clinical factor in newly diagnosed diffuse large B-Cell Lymphoma and has implication for bias in clinical trials. Journal of Clinical Oncology 36:1603-1610, 2018
- Somkin CP, Ackerson L, Husson G, et al: Effect of medical oncologists' attitudes on accrual to clinical trials in a community setting. Journal of Oncology Practice 9:e275-e283, 2013
- American Cancer Society Cancer Action Network: Barriers to patient enrollment in therapeutic clinical trials for cancer: A landscape report. 2018

Financial Barriers for Patients

There are many barriers to patient enrollment on clinical trials, with financial burden is an important factor. Check out the links below to learn about the reasons, including rising cost of cancer care and lack of transparency in coverage policy, and how to overcome them.

- Unger JM, Gralow JR, Albain KS, et al: Patient income level and cancer clinical trial participation: A prospective survey study. JAMA Oncology 2:137-139, 2016
- Winkfield KM, Phillips JK, Joffe S, et al: Addressing financial barriers to patient participation in clinical trials: ASCO policy statement. Journal of Clinical Oncology 10.1200/JCO.18.01132

Representation of Underserved Populations

In many cancer clinical trials, specific patient populations are not appropriately represented, which limits the applicability of their results to the general public. The study linked to below sought to determine representation of ethnic minorities and women in cancer clinical trials.

- Duma N, Vera Aguilera J, Paludo J, et al: Representation of minorities and women in oncology clinical trials: Review of the past 14 years. Journal of Oncology Practice 14:e1-e10, 2018

Geographic Barriers

Geographic location is another factor that can impact clinical trial accrual. Several studies, linked to below, have sought to examine how geographic distribution affects cancer outcomes and accessibility to clinical trials.

- Unger JM, Moseley A, Symington B, et al: Geographic distribution and survival outcomes for rural patients with cancer treated in clinical trials. JAMA Network Open 1:e181235, 2018
- Virani S, Burke L, Remick SC, et al: Barriers to recruitment of rural patients in cancer clinical trials. Journal of Oncology Practice 7:172-177, 2011
- Galsky MD, Stensland KD, McBride RB, et al: Geographic accessibility to clinical trials for advanced cancer in the United States. JAMA Internal Medicine 175:293-295, 2015

Broadening Eligibility Criteria

Eligibility criteria are vital for success and patient safety in clinical trials, but excessive criteria can affect trial accrual. Review the resources below to learn about current initiatives to broaden eligibility criteria.

- Clinical Trial Eligibility Criteria. American Society of Clinical Oncology – ASCO and Friends of Cancer Research began a joint partnership in 2016 to broaden eligibility criteria to make clinical trials more representative. Learn more about this initiative and the resulting publications.
- Kim ES, Bruinooge SS, Roberts S, et al: Broadening eligibility criteria to make clinical trials more representative: American Society of Clinical Oncology and Friends of Cancer Research joint research statement. Journal of Clinical Oncology 35:3737-3744, 2017
- Beaver JA, Ison G, Pazdur R: Reevaluating eligibility criteria – Balancing patient protection and participation in oncology trials. The New England Journal of Medicine 376:1504-1505, 2017

Recruitment and Enrollment Strategies

The resources below will aid in developing strategies to improve and streamline recruitment and enrollment in your clinical trial program.

- Huang GD, Bull J, Johnston McKee K, et al: Clinical trials recruitment planning: A proposed framework from the Clinical Trials Transformation Initiative. Contemporary Clinical Trials 66:74-79, 2018
- Rubin EH, Scroggins MJ, Goldberg KB, et al: Strategies to maximize patient participation in clinical trials. Am Soc Clin Oncol Ed Book 216-221, 2017
- Society for Clinical Research Sites (SCRS): White Papers: Recruiting diverse patient populations in clinical studies: Factors that drive site success.
- Forte Research: Patient recruitment in clinical trials: Steps to develop a successful enrollment strategy. 2017
- National Cancer Institute (NCI): AccrualNet – Online resource with strategies, tools, and resources to support accrual to clinical trials.
- Increasing clinical trial accrual: Collaboration and physician-to-physician contact. Journal of Oncology Practice 3:152-153, 2007.
- Powell BL, Olson D, Morrell RM, et al: Increasing clinical trials accrual at a comprehensive cancer center. Blood 124:1266, 2014.

Resources for Engaging Patients in Clinical Trials

The following tools, research, and other resources will help you create or improve your existing strategies for engaging patients in clinical trials.

- American Society of Clinical Oncology: Clinical Trial Resources.
- Research Advocacy Network: Advocacy program research awareness event tool kit for community cancer centers.
- Perlmutter J, Roach N, Smith ML: Involving the patient/advocate in research. Seminars in Oncology 42:681-685, 2015
- Education Network to Advance Cancer Clinical Trials (ENACCT), Community-Campus Partnerships for Health (CCPH): Communities as partners in cancer clinical trials: Changing research, practice and policy. 2008
- Michaels M, Blakeney N, Langford AT, et al: Five principles for effective cancer clinical trial education within the community setting. Journal of Cancer Education 30:197-203, 2015
- Perlmutter J, Bell SK, Darien G: Cancer research advocacy: Past, present, and future. Cancer Research 73:4611-4615, 2013

Professional Organizations Supporting Researchers and Research

The resources below list examples of professional and research organizations that provide information, resources, and opportunities for researchers. The list is not exhaustive.

- American Society of Clinical Oncology (ASCO) | A professional organization for physicians and oncology professionals caring for people with cancer
- Association of American Cancer Institutes' Clinical Research Initiative (AACI-CRI) | A network for cancer center clinical research leaders
- Society for Clinical Research Sites (SCRS) | A trade association that represents the global clinical research sites and focuses on site sustainability. They have helpful resources for research sites, including a series of white papers
- Association for Clinical Research Professionals (ACRP) | A professional organization that supports clinical research professionals through membership, training and development, and certification
- Oncology Nursing Society (ONS) | ONS has special interest groups (SIGs) on various topics, including clinical trials
- International Association of Clinical Research Nurses | A non-profit nursing organization with website for resources and toolkits for research professionals
- Society for Clinical Research Associates (SoCRA) | A non-profit organization dedicated to educating and developing clinical research professionals
- Regulatory Affairs Professionals Society (RAPS) | A non-profit organization that supports regulatory professionals

ASCO Library of Clinical Trial Resources for Research Sites

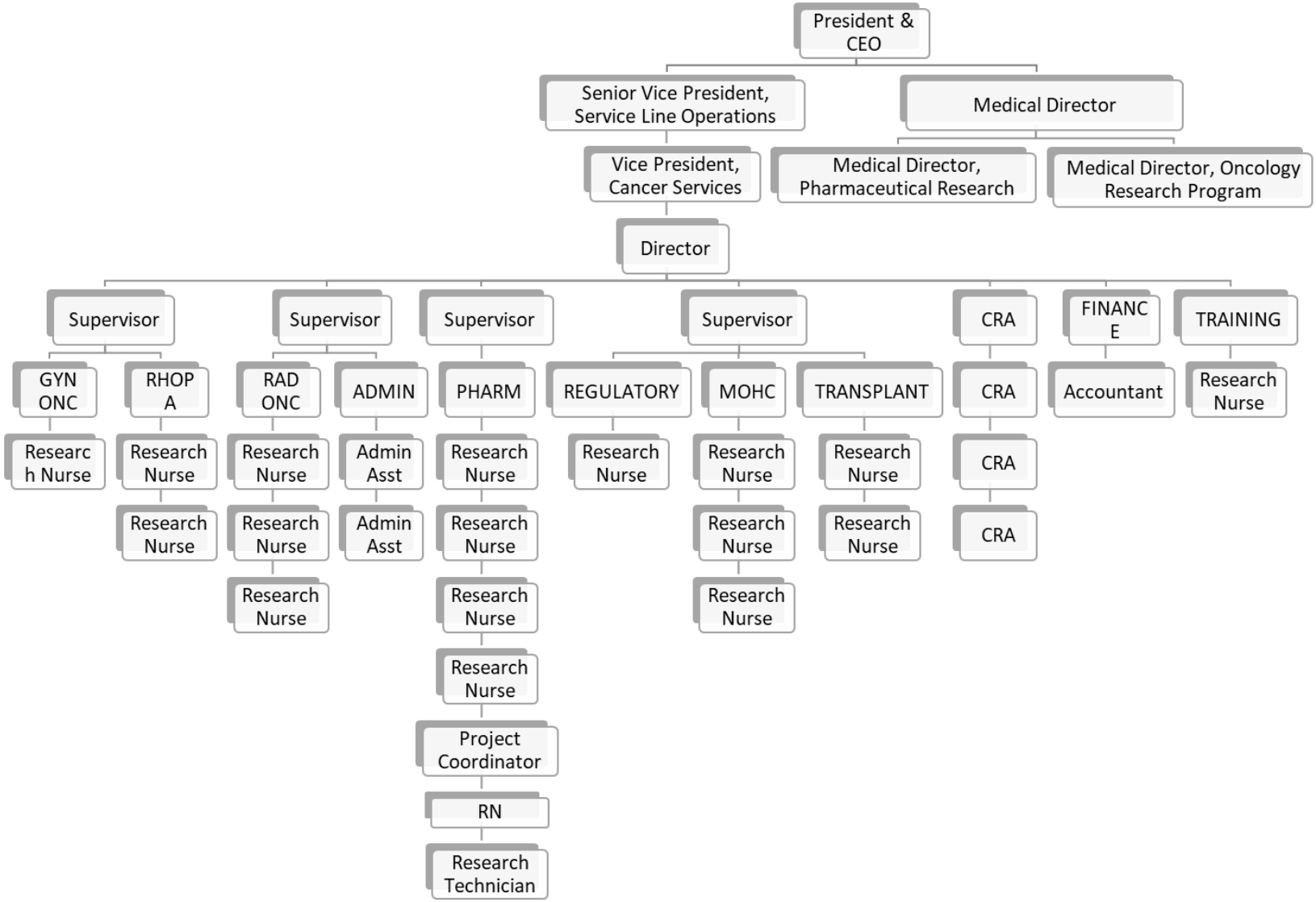
The ASCO Library of Clinical Trial Resources serves as a central location for links, tools, and other resources to support physician investigators and research staff in conducting and managing clinical trials. A Task Force of the ASCO Research Community Forum, representing a range of community research stakeholder groups with a wealth of research experience, compiled this list to help make it easier for research sites to find needed resources. The library covers content in the categories below.

Access the library of resources at https://www.asco.org/node/9906.

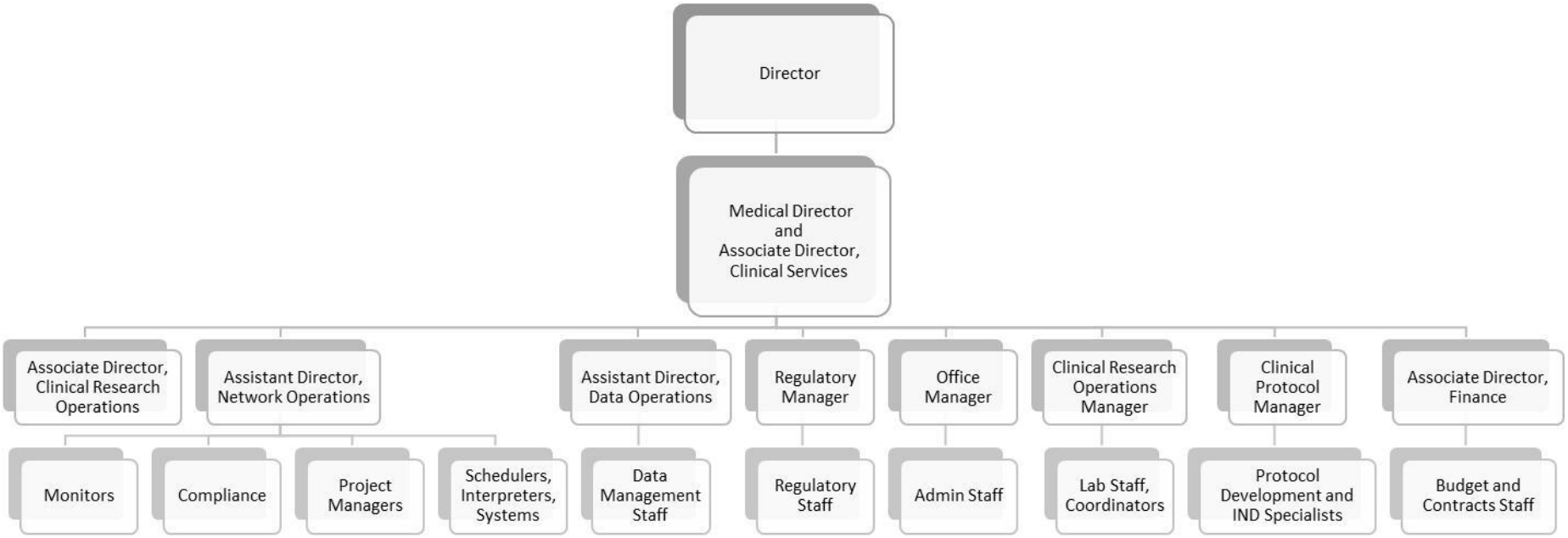
If you have ideas for additional content, please email *researchcommunityforum@asco.org*.

APPENDIX A: ORGANIZATION CHARTS FOR A RESEARCH PROGRAM

SAMPLE ORGANIZATION CHART FOR A RESEARCH PROGRAM



SAMPLE ORGANIZATION CHART FOR A RESEARCH PROGRAM



APPENDIX B: CLINICAL TRIAL RESEARCH STAFF POSITION DESCRIPTIONS

JOB DESCRIPTION: CLINICAL RESEARCH NURSE

[NAME OF INSTITUTION OR LOGO]

JOB DESCRIPTION

JOB TITLE:	**CLINICAL RESEARCH NURSE**		
Job Code:		**Dept./Cost Center:**	
Reports to (Title):	Clinical Trials Manager	**Employment Type:**	Full-time

GENERAL SUMMARY OF POSITION

Under the guidance and supervision of the Principal Investigator, the Clinical Research Nurse coordinates study activities throughout the trial to assure that the integrity and quality of the clinical research trial is maintained and that the trial is conducted in accordance with federal, state and local regulations, the sponsor protocol and other sponsor requirements, institutional policies and good clinical practice (GCP) guidelines and may assist in the design of the clinical research. (The description, roles and training can be modified to include levels of responsibility such as CRN I, CRN II, Senior CRN.)

PRINCIPAL ROLES AND RESPONSIBILITIES

This is a brief description of the essential roles, responsibilities and activities which are typically performed by this position. Job details are located in the appropriate manual of operations.

- Maintains knowledge and understanding of federal and international regulations and guidelines and institutional policies governing human subject research and incorporates them in the conduct of research and care of participants;
- Proficiently exhibits problem solving skills and the ability to multi-task, managing multiple assignments in a timely manner while maintaining quality standards and meeting assessed goals;
- Proficiently coordinates multiple clinical trials:
    - Ensuring the study team is capable of performing the procedures required of each study protocol or provide training as appropriate;
    - Identifying and procuring the equipment and supplies needed to fulfill project requirements;
    - Optimally recruit candidates and appropriately screen for eligibility;
    - Ensuring ongoing informed consent of study participants;
    - Ensuring study required events occur per protocol, including the right event at the right time using the right method with appropriate documentation or report as a protocol deviation;
    - Working with the investigator, observe for and appropriately report and follow adverse events;
    - Providing the sponsor with quality data having reviewed the data for ALCOA principles;
    - Appropriately preparing, maintaining and archiving documents related to the clinical trial;
    - Maintaining open and positive communications with human subjects, investigators, research staff, sponsors, appropriate departments and other entities involved in the research project;
    - Participating in periodic site visits from sponsor, regulatory authorities and others;
- Proficiently performs regulatory activities or assistance with activities as required which may include Sponsor submissions and IRB applications, amendments, continuing reviews and event reports;

- Proficiently functions as a departmental resource regarding clinical trials operations at a level appropriate to this position;
- Proficiently assists in processing new research proposals and in budget and contract negotiations at a level appropriate to this position and as required;
- Proactively evaluates processes for quality improvement;
- Develops and achieves personal and professional goals such as identifying and participating in new learning opportunities to sustain and enhance professional development and maintaining professional certifications, licensure and credentialing as required;

EDUCATION AND/OR TRAINING

Graduate of an approved nursing program, BSN preferred

LICENSURE/ CERTIFICATION/ REGISTRATION

Registered nurse, Certified discipline specific

MINIMUM EXPERIENCE AND PREFERRED KNOWLEDGE, ABILITIES AND SKILLS

Required time in field previous to employment: Three (3) years of experience in clinical research.
(Level I = 0 years, Level II = 1 year, Level III = 5 years, Senior Level = 10 years)

JOB DESCRIPTION: CLINICAL RESEARCH COORDINATOR

[NAME OF INSTITUTION OR LOGO]

JOB DESCRIPTION

JOB TITLE:	**CLINICAL RESEARCH COORDINATOR**		
Job Code:		**Dept./Cost Center:**	
Reports to (Title):		**Employment Type:**	Full-time

GENERAL SUMMARY OF POSITION

This position provides support and coordination for clinical research studies (Entry level CRC: basic support and coordination) (Senior CRC: independent coordination of and leadership for multiple, complex clinical research studies) in order to ensure the efficiency and accuracy of clinical studies through all stages as the study progresses and shows vigilance in participant safety, protocol compliance, and data quality. (Senior CRC: This position may also provide leadership to lower-level clinical research coordinators and/or other support personnel.

PRINCIPAL ROLES AND RESPONSIBILITIES

This is a brief description of the essential roles, responsibilities and activities which are typically performed by this position. Job details are located in the appropriate manual of operations.

- Has knowledge of and follows good clinical practice, FDA, OHRP, HIPAA policies
- Conducts all research related activities in compliance with institutional policies
- Assist in the design of study documents such as flow sheets, data forms and source document worksheets
- Participate in the planning, development, and budgeting for clinical studies
- Assist in the preparation of study start-up documents
- Understands and follows policies regarding the informed consent process
- Conducts recruitment activities as required to achieve expected study enrollment
- Prescreen, recruit and screen study participants and coordinate their protocol specified study visit activities and help facilitate their continued participation
- Maintain subject logs, research charts and study binders
- Assure collection, processing and shipment of any protocol required samples for local or central laboratory analysis
- Maintain study supply inventory
- Monitors patient health adverse events and for serious adverse events (SAE) and reports events per protocol requirements
- Collect and submit source data per protocol requirements, maintaining data quality
- Resolve research data queries
- Organize and maintain all required research documentation
- Assist with regulatory documentation and IRB submissions
- Assist in the preparation for and participates in the conduction of audits/monitoring visits as required

EDUCATION AND/OR TRAINING

Allied health degree or Associates degree in Clinical Trials Research related curriculum plus a minimum of five years clinical and/or research experience;
OR
Bachelor's degree in health science and a minimum of three years clinical and/or research experience. Master's degree replaces two years of needed experience.
OR
High School Diploma and a minimum of seven years of clinical and/or research experience with comprehensive knowledge of clinical trial processes, comprehensive knowledge of data collection and storage and research principles, including 7 years of human clinical research experience. Association of Clinical Research Professionals (ACRP) or Society of Clinical Research Associates (SOCRA) Certification is required at time of hire.

LICENSURE/ CERTIFICATION/ REGISTRATION

CCRC or CCRP preferred

MINIMUM EXPERIENCE AND PREFERRED KNOWLEDGE, ABILITIES AND SKILLS

- Experience working with patients or study subjects.
- Training or experience in the conduct of clinical research trials.
- Excellent verbal and written communications and presentation skills; excellent organizational skills; and excellent interpersonal skills to work effectively in a diverse team.
- Proficiency with Microsoft Word, PowerPoint, and Windows.
- Excellent analytical and problem-solving skills.
- Ability to work effectively in a fast-paced, team-based environment; project management and coordination skills; ability to prioritize tasks and meet multiple deadlines on concurrent projects.
- Ability to establish cooperative working relationships with patients, co-workers, & physicians.
- Demonstrated proficiency with medical terminology.
- Ability to abstract data from medical records and transfer it to data collection forms or directly into databases.

JOB DESCRIPTION: REGULATORY COORDINATOR

[NAME OF INSTITUTION OR LOGO]

JOB DESCRIPTION

JOB TITLE:	**REGULATORY COORDINATOR**		
Job Code:		**Dept./Cost Center:**	
Reports to (Title):		**Employment Type:**	Full-time

GENERAL SUMMARY OF POSITION

The Regulatory Coordinator is responsible for overseeing the day -to-day regulatory management of all types of clinical research protocols. The position will manage all aspects of study start-up, modification submissions, continuous reporting, and study close-out to the Institutional Review Board (IRB) and any relevant regulatory agencies including, the Institutional Biosafety Committee, the institutional Radiation Safety Committee, and the clinical trial sponsor, funding foundation, or governmental agency.

PRINCIPAL ROLES AND RESPONSIBILITIES

This is a brief description of the essential roles, responsibilities and activities which are typically performed by this position. Job details are located in the appropriate manual of operations.

- Manage day-to-day regulatory operations and workload of regulatory team, plan resource needs and strategize growth.
- Provide regulatory support INSTITUTION programs and oversee maintenance of all required regulatory documents.
- Provide regulatory start-up support for research teams for all types of clinical trials.
- Partner with study teams to provide ad hoc regulatory management for ongoing clinical trials.
- Oversee timely regulatory submissions to meet project timelines.
- Create and maintain position related Standard Operating Procedures (SOPs) and ensures procedural compliance.
- Identify program improvement opportunities and lead improvement efforts within team, including technology solutions; identify opportunities for expanding solutions to study teams.
- Coordinate with appropriate department to address regulatory-related quality and compliance matters.
- Assist with the development of standard regulatory-related training requirements and with ongoing education and training for investigators and research personnel.
- Perform internal audits and quality assurance reviews on regulatory files, as needed
- Write and edit clinical research protocol consent forms in accordance with federal regulations and guidelines and good clinical practice (GCP) guidelines.
- Liaise with appropriate personnel, departments and outside entities on clinical trial regulatory operations.

EDUCATION AND/OR TRAINING

Bachelor's degree in Clinical Health Science, Health Administration or related field required.

LICENSURE/ CERTIFICATION/ REGISTRATION

LICENSURE, REGISTRATION AND/OR CERTIFICATION REQUIRED BY LAW:
None

LICENSURE, REGISTRATION AND/OR CERTIFICATION REQUIRED BY INSTITUTION ONLY:
Certification in clinical research from the Society of Clinical Research Associates (SoCRA) or the Association of Clinical Research Professionals (ACRP) required or must be obtained within one (1) year of assuming the position.

MINIMUM EXPERIENCE AND PREFERRED KNOWLEDGE, ABILITIES AND SKILLS

Required time in field previous to employment: Three (3) years' experience in clinical research.

SPECIAL SKILLS, KNOWLEDGE AND ABILITIES:

- Must understand clinical trial and research regulatory processes.
- Able to prioritize work and work with departments and study teams over a variety of projects.
- Able to exercise good judgment on a range of issues and to manage overlapping and complex projects through to completion.
- Must have excellent interpersonal and communication skills as well as organizational and writing skills.
- Must be adept at computer usage including knowledge of word processing and data base software with an ability to learn various project databases.
- Must have experience with electronic health record systems and clinical trial management systems.

JOB DESCRIPTION: FINANCE AND BILLING MANAGER

[NAME OF INSTITUTION OR LOGO]

JOB DESCRIPTION

JOB TITLE:	**FINANCE AND BILLING MANAGER**		
Job Code:		**Dept./Cost Center:**	
Reports to (Title):		**Employment Type:**	Full-time

GENERAL SUMMARY OF POSITION

Financial and billing manager of clinical research studies to include maintenance of financial records, invoice processing and management, monthly financial reporting and support for budget negotiations, financial forecasting, monitoring monthly budget expenditures and identifying process improvements.

PRINCIPAL ROLES AND RESPONSIBILITIES

This is a brief description of the essential roles, responsibilities and activities which are typically performed by this position. Job details are located in the appropriate manual of operations.

- Maintains current knowledge of federal and state claim processing regulations with regard to clinical trials.
- Responsible for financial management of studies to include timely and accurate invoice processing (start-up, milestone, pass-through, ad-hoc) and maintenance of payment files using appropriate tools and software.
- Maintains all financial records for the oncology research department and works in partnership with other departments as necessary, such as Patient Access, Revenue Cycle Management, and Corporate Accounting.
- Prepares monthly financial reports and assists the clinical research manager in monitoring monthly budget expenditures.
- Develops tracking mechanism to report financial study key indicators.
- Assists the Clinical Research Manager in identifying process improvements to decrease cost and increase revenue.
- Performs close out reconciliation on all ended studies and ensures that no invoices are outstanding and that all milestones are collected.
- Collaborates with manager in budget and payment schedule negotiations with sponsor.
- Analyzes study budgets and assists manager in financial forecasting.

EDUCATION AND/OR TRAINING

Bachelor's degree from a four-year college or university

LICENSURE/ CERTIFICATION/ REGISTRATION

NONE

MINIMUM EXPERIENCE AND PREFERRED KNOWLEDGE, ABILITIES AND SKILLS

- Two years' experience in a financial setting or equivalent combination of education and experience.

- COMMUNICATION: Uses appropriate methods to clearly convey information to others in an engaging way, which helps others understand and retain the message.
- COLLABORATION: Works with others respectfully and openly; provides help to achieve shared goals.
- SERVICE: Anticipates and meets or exceeds all patient/customer needs and pro-actively takes responsibility for ensuring their quality care experiences. All co-workers will be held to standards and behaviors guided by the INSTITUTION goals.
- SAFETY: Meets or exceeds patient and co-worker safety requirements while promoting and achieving quality outcomes.
- ACCOUNTABILITY: Takes ownership for goals and outcomes; effectively and efficiently uses available resources to successfully complete tasks.

JOB DESCRIPTION: CLINICAL RESEARCH TECHNICIAN

[NAME OF INSTITUTION OR LOGO]

JOB DESCRIPTION

JOB TITLE:	**CLINICAL RESEARCH TECHNICIAN**		
Job Code:		**Dept./Cost Center:**	
Reports to (Title):		**Employment Type:**	Full-time

GENERAL SUMMARY OF POSITION

Under the direction of the primary study coordinator and/or supervisor, assists with the implementation of clinical research activities ensuring adherence to protocol requirements, in accordance with federal research regulations. The primary function of this position is to carry out screening, recruitment, and consenting of research protocol participants on non-treatment protocols. Duties will include obtaining, collecting, processing, and shipment of human biological specimens and research data. In addition to research activities, the research technician will be responsible for front desk activities including clerical support, file maintenance, daily courier rounds, and maintaining/ordering office and specimen collection supplies.

PRINCIPAL ROLES AND RESPONSIBILITIES

This is a brief description of the essential roles, responsibilities and activities which are typically performed by this position. Job details are located in the appropriate manual of operations.

- Assists the research team in assigned research study activities according to ability such as activities related to start-up, pre-screening, recruitment, eligibility, screening, study visits and study termination.
- Maintains protocol related supplies and equipment and maintains and supplies office equipment as required.
- Maintains investigational items temperature logs as required.
- Assists the research team in coordinating and obtaining biological specimen collections.
- Performs vein puncture (phlebotomy) on study participant per protocol requirements.
- Processes, ships and logs protocol required biological specimens, monitoring for delivery, while maintaining compliance with the protocol and federal regulations.
- Collects protocol and CRF required participant data including abstraction from medical records and other source data as requested.
- With assistance, submits protocol required imaging to study sponsors.
- Maintains study specific correspondence, source documents and other study required documents.
- Enters study data into the data system such as the Case Report Form per protocol requirements.
- Maintain participant records and file system; make copies as required, de-identify charts as required.
- Provide clerical support including copying, filing, faxing, phone messaging, and paging.
- Prepares subject chart for study visit. Preassembles blank participant charts.
- Obtain physician/investigator signatures on documents as assigned.
- Perform assigned work safely, adhering to established departmental safety rules and practices; report to supervisor, in a timely manner, any unsafe activities, conditions, hazards, or safety violations that may cause injury to oneself, other employees, protocol participants and visitors.

- Perform other related duties as required.

EDUCATION AND/OR TRAINING

High School graduate with one (1) year of clerical or secretarial experience required. Medical assistant and phlebotomy experience preferred. An equivalent combination of education and experience may be substituted.

LICENSURE/ CERTIFICATION/ REGISTRATION

NONE

MINIMUM EXPERIENCE AND PREFERRED KNOWLEDGE, ABILITIES AND SKILLS

- Computer skills necessary to accomplish the principal duties and responsibilities listed above, using the existing hardware, software and peripherals available within the department including the processing documents and spreadsheets.
- Ability to be trained in the operation of special equipment as required by protocol.
- Ability to prioritize, plan and organize work; communicate verbally and in writing; proofread or edit material; perform arithmetical and simple calculations; and maintain confidentiality of information.
- Ability to function independently and as a team member.
- Ability to be self-motivated.
- Ability to coordinate simultaneous procedures with accuracy.
- Skill in oral and written communication.
- SPECIAL REQUIREMENTS: Completion of Human Subjects Protection, Good Clinical Practice, Shipment of Infectious -Substances and Biological Substances and other mandatory certifications required within 6-months of position start date.

JOB DESCRIPTION: RESEARCH DATA MANAGER

[NAME OF INSTITUTION OR LOGO]

JOB DESCRIPTION

JOB TITLE:	**RESEARCH DATA MANAGER**		
Job Code:		**Dept./Cost Center:**	
Reports to (Title):		**Employment Type:**	Full-time

GENERAL SUMMARY OF POSITION

Clinical research data specialist ensures that clinical trials data is collected, managed and reported clearly, accurately and securely.

PRINCIPAL ROLES AND RESPONSIBILITIES

This is a brief description of the essential roles, responsibilities and activities which are typically performed by this position. Job details are located in the appropriate manual of operations.

- Review data query responses
- Identify and report data discrepancies
- Assist in the maintenance of a system for collecting protocol data.
- Document study specific information appropriately in the patient medical record.
- Enter protocol-specific data points into the appropriate database.
- Review data forms for completeness and updates as needed.
- Create, print, and distribute forms using computer and printer.
- Utilize computer for word processing, spread sheets and retrieve patient data.
- Request patient charts via on-line system as necessary to facilitate research projects.
- Obtain and returns charts to medical records when requested.
- Generate reports as requested.
- Monitor informed consent files to assure they are up to date.
- Assist with annual reviews, updates, and response data, and generates reports as requested.

EDUCATION AND/OR TRAINING

High school diploma or equivalent required. Associate's or bachelor's degree in a science, computer, or business related field preferred.

LICENSURE/ CERTIFICATION/ REGISTRATION

Certification in clinical research preferred

MINIMUM EXPERIENCE AND PREFERRED KNOWLEDGE, ABILITIES AND SKILLS

Two years of related experience. May substitute required experience with completed years of college on a one to one basis.

- Previous experience working with data.
- Versatile communication skills.

- A willingness to work with others.
- Strong technical skills including fluency with requisite computer applications.
- Ability to project plan and prioritize.
- Demonstrated ability to define, break down, and solve problems.
- Enthusiasm for learning new skills at a rapid pace.
- Resilience, strong work ethic and outcomes orientation.

APPENDIX C: SAMPLE CAREER LADDER FOR A CLINICAL RESEARCH ASSOCIATE (CRA)

Used with permission from Jamie Harper, Illinois Cancer Center

Data Manager

- High school diploma
- 2 years in a medical setting (preferably research)
- Familiar with medical terminology
    - Data Manager to CRA I track (internal department candidates only)-
        - College courses completed in science or healthcare related field (ie- medical terminology, anatomy & physiology, pharmacology, etc.)
        - CRA Certificate from the CRA Training Institute
        - 3 years experience as Data Manager
        - Oncology theory training initiated
        - CCAT testing required

CRA I (entry level CRA)

- New employees with no research experience
- 0-2 years of clinical research experience
- Bachelor's Degree in a science or healthcare related field or equivalent experience

CRA II (CRA)

- 2-5 years of clinical research experience
- Completed all new employee training
- Late data- 10% based on internal audits
- Error rate- 10% based on internal audits
- Total credits enrolled- 25% (Navigators Only)

CRA III (Senior CRA)

- ≥5 years of clinical research experience
- SoCRA certified
- Cross training completed
- Understanding of regulatory (IRB, GCP, FDA, etc) requirements
- Involved in an oversight/leadership task (late data, queries, etc.)
- Late data- <10% based on internal audits
- Error rate- <10% based on internal audits
- Total credits enrolled- >25% (Navigators Only)

Lead CRA (at Management Discretion)

- ≥5 years of clinical research experience
- SoCRA certified
- Proficient at all aspects of the Clinical Research Associate position
- Thorough understanding of regulatory (IRB, GCP, FDA, etc.) requirements
- Attended at least one leadership training session
- Proven ability to handle multiple job functions
- Excellent communication skills and presentation abilities
- Ability to complete a special project (poster presentation, efficiency/process improvement, etc.)

APPENDIX D: RESEARCH NURSE COORDINATOR TRAINING AND ORIENTATION TOOL

[INSTITUTION]
RESEARCH NURSE COORDINATOR ORIENTATION CHECKLIST
Used with Permission from Nancy Burns, UNC Rex Cancer Center

Employee Name:
Date of Hire:

Training	Item	Completion Date	Employee/ Supervisor Initials
Basic Training	☐ Pre-Orientation Checklist Initiated ☐ Research Department Checklist ☐ Collaborative Institutional Training Initiative (CITI) Training: o Basic Course o Good Clinical Practice for Research (GCP) o HIPAA o Once finished – submit certificates to Office of Clinical Research ☐ Training in institutional standard operating procedures (SOP) ☐ If applicable, National Cancer Institute's (NCI) *Cancer Clinical Trials: The In-Depth Program* https://accrualnet.cancer.gov/sites/accrualnet.cancer.gov/files/InDepth_Book_m.pdf ☐ Viewing of institutional abbreviations and acronyms ☐ Password tracking ☐ If applicable, training in Structure of Cancer Clinical Trial organizations, Cooperative groups & Pharmaceutical sponsors		
CCHS Office of Sponsored Programs (OSP)	☐ Compete conflict of interest (COI) online form (renew annually) ☐ Effort reporting		
Education Center	☐ International Air Transport Association (IATA) (bio specimen shipping) online training. ☐ Provide IATA certificate to Office of Clinical Research ☐ Other assigned online training as instructed		
INSTITUTIONAL Training Manual	☐ See INSTITUTIONAL training manual		
If applicable: Oncology Fundamentals	☐ Staging: AJCC Staging Manual; (Surveillance, Epidemiology, and End Results) SEER online module http://training.seer.cancer.gov/staging/ & www.Cancer.org https://cancerstaging.org/references-tools/quickreferences/Pages/default.aspx) ☐ Treatment modalities (Oncology Nursing Society (ONS) Core Curriculum Text)		

[INSTITUTION]
RESEARCH NURSE COORDINATOR ORIENTATION CHECKLIST
Used with Permission from Nancy Burns, UNC Rex Cancer Center

Employee Name:
Date of Hire:

	☐ Treatment guidelines by site http://www.nccn.org/professionals/physician_gls/f_guidelines.asp#site ☐ Treatment toxicities and adverse events: Common Terminology Criteria for Adverse Events (CTCAE) https://ctep.cancer.gov/protocolDevelopment/electronic_applications/ctc.htm ☐ Pathology reports (National Cancer Institute (NCI) handout) ☐ Response Evaluation Criteria in Solid Tumors Version 1.1 (RECIST) (see journal article & ECOG Learning Tool) ☐ Molecular biology of cancer http://www.merckmanuals.com/professional/hematology-and-oncology/overview-of-cancer/cellular-and-molecular-basis-of-cancer ☐ Genetic considerations in cancer and treatment http://www.cancer.gov/about-cancer/causes-prevention/genetics		
Basic Pharmacology	☐ Pharmacokinetics/Pharmacodynamics (PK/PD)		
Clinical Research Fundamentals	☐ Types and phases of clinical research ☐ The clinical research protocol-key elements ☐ The informed consent-key elements ☐ Roles and responsibilities of the clinical research team http://ori.hhs.gov/TheResearchClinic ○ Principal Investigator (PI) ○ Physician office staff ○ Research Nurse Coordinator ○ Research Nurse Supervisor ○ Clinical Research Associate (CRA) ○ Research Pharmacy ○ Financial		
Regulatory	☐ FDA http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/default.htm ○ 1572 ○ Delegation of Authority (DOA) ☐ Institutional Review Board (IRB) http://www.christianacare.org/irb ☐ Central Institutional Review Board (CIRB) ☐ Regulatory RN Responsibilities		

[INSTITUTION]
RESEARCH NURSE COORDINATOR ORIENTATION CHECKLIST
Used with Permission from Nancy Burns, UNC Rex Cancer Center

Employee Name:
Date of Hire:

	☐ Research Nurse Responsibilities regarding amendments, yearly reviews, etc. ☐ HIPAA ☐ Audits ☐ Drug Accountability (DARFs) ☐ SOPs ☐ Regulatory Protocol Binders		
Study Activities	☐ Site Activation including regulatory activities and review of resources ☐ Learning a new protocol ☐ Mandatory training for clinical research staff and clinical staff ☐ Prescreening ☐ Screening ☐ Eligibility ☐ Informed consent (OHRP: General Informed Consent Requirements video: https://youtu.be/URo4x4pv68A?list=PL5965CB14C2506914) ☐ Enrollment/Registration ☐ Making a research (shadow) chart and keeping it "audit ready" ☐ Ordering pathology specimens ☐ Protocol Forms ☐ Communication ☐ Pre-treatment labs, assessments (performance status) ☐ Treatment ☐ Documentation of study visits, phone conversations and other patient contact ☐ Source documentation ☐ Case Report Forms (CRF / eCRF) ☐ Toxicity Assessment and the CTCAE ☐ Definition and reporting of Serious Adverse Events (SAEs) ☐ Oral medication documentation ☐ Drug accountability ☐ Laboratory and specimen collection, processing, de-identification & shipping		

[INSTITUTION]
RESEARCH NURSE COORDINATOR ORIENTATION CHECKLIST
Used with Permission from Nancy Burns, UNC Rex Cancer Center

Employee Name:
Date of Hire:

	☐ Consent withdrawal ☐ Queries ☐ Deviations		
Interdisciplinary Communication	☐ Physician office schedules for screening ☐ Tumor conferences ☐ Use of Outlook or other tracking method for patient follow-up ☐ Treatment Team/Clinical Staff ○ Medication verification and documentation ○ Verbal communication with treating investigator ○ Pharmacy ○ CRA regarding bio-specimen processing ○ Physician office staff		
Shadow or Observation Experience *(Complete an observation worksheet for each)*	☐ Regulatory RN ☐ Regulatory Admin ☐ Research Nurse Supervisor(s) ☐ Pharma Research Nurse ☐ CRA ☐ Oncology Patient Advocates for Clinical Trials (OPACT) ☐ IRB ☐ Others as directed		
Areas requiring additional training	☐ Radiation Oncology ☐ Pharmaceutical studies ☐ Prevention/Cancer Control ☐ Infusion treatment center ☐ Clinical laboratory ☐ GYN oncology ☐ Regulatory		
Audit Preparation	☐ Basics of audit process		

[INSTITUTION]
RESEARCH NURSE COORDINATOR ORIENTATION CHECKLIST
Used with Permission from Nancy Burns, UNC Rex Cancer Center

Employee Name:
Date of Hire:

On-call Requirement	☐ Research team mobile phone		

Demonstration of Key Activities, Accountabilities & Competencies	**Activity/Measurement Criteria** ***Must be conducted in accordance with specific protocol, hospital, and federal regulations.**	**Comments: U-Unsatis-factory NI-Needs Improve-ment ME-Meets Expectation**	**Date/Preceptor Initials**
Protocol Management & Compliance ***Conduct of Research***	☐ Prescreens patient and communicates information to treating investigator ☐ Maintains screening logs ☐ Adopts an organization system for daily workflow ☐ Prioritizes activities appropriately ☐ Delegates as needed		
	☐ Coordinates screening and documents appropriately		
	☐ Obtains Informed Consent and documents appropriately		
	☐ Creates an Eligibility worksheet		
	☐ Determines eligibility with 2nd RN review and obtains treating investigator verification and documents appropriately		
	☐ Enrolls/Registers/Randomizes patient and documents appropriately		
	☐ Documents in DDOTS/Credit system		
	☐ Provides Patient Education regarding: ○ clinical trial participation ○ ongoing nature of informed consent ○ schedule and treatment ○ medication administration and patient documentation ○ safe handling of oral chemotherapy ○ key contact information		

[INSTITUTION]
RESEARCH NURSE COORDINATOR ORIENTATION CHECKLIST
Used with Permission from Nancy Burns, UNC Rex Cancer Center

Employee Name:
Date of Hire:

	○ documents appropriately ○ Provides IRB approved study updates		
	☐ Pre-treatment: ○ Verifies study medication and other orders prior to treatment. ○ Reviews ▪ Labs ▪ EKG ▪ Performance status ▪ Concomitant medication list, ▪ Toxicity assessment (uses the CTCAE to grade AE) with treating investigator. ○ Confirms that patient meets criteria for treatment per protocol or ensures that dose modification or discontinuation occurs per protocol. ○ Communicates with Research Pharmacy regarding treatment plan in a timely manner. ○ Completes documentation in a timely manner. ○ Provides verbal and written communication to physician. ○ Provides pill diary/calendar to patient if needed ○ Verifies oral study medication with 2nd RN. ○ Documents pill count in progress note. ○ Ensures drug accountability with Research Pharmacist.		
	☐ Reports AEs to PI, sponsor and other research team members ☐ Completes SAE submission within required time period.		
	☐ Responds and completes query response in a timely manner		
	Completes Documentation within expected timeframes ○ Eligibility ○ Consent ○ Treatment ○ SAE ○ Deviation		

[INSTITUTION]
RESEARCH NURSE COORDINATOR ORIENTATION CHECKLIST
Used with Permission from Nancy Burns, UNC Rex Cancer Center

Employee Name:
Date of Hire:

	☐ Obtains study re-consent when necessary		
	☐ Completes consent-withdrawal procedure, if necessary		
	☐ Clinical Staff Education ○ Provides research topic education to ambulatory infusion staff and/or hospital staff		
Disease Team Communication and Participation	☐ Actively participates in Disease Team Meetings ☐ Serves as the primary medical person to interpret the protocol to medical and nursing staff, particularly related to dose, concomitant medications, and safety issues related to the administration of the study drug or treatment. ☐ Communicates with Research Pharmacy, treating providers, clinical nursing, and others to ensure an excellent patient experience. ☐ Coordinates data collections and enters data into sponsor data base for analysis. ☐ Assists with the preparation of documents for audit and review by sponsors, regulatory agencies, and internal and external review boards.		
Nursing Team Participation	☐ Demonstrates willingness to assist colleagues, including other Research RNs, with workload, education, and training.		

Employee Signature
Date

Preceptor/Mentor Signature
Date

Supervisor Signature
Date

APPENDIX E: JOB DESCRIPTION/PERFORMANCE REVIEW

Used with permission from Kandie Dempsey, Christiana Care Health System

NAME:	DEPT:	COST CENTER:
TITLE: Research Coordinator	CODE: 32165	GRADE: NO704

PART I: Competency Review

INSTRUCTIONS: Please circle the appropriate rating code, add comments at the end to individualize the document. Comments must be added for all reviews of below standards or role model to specifically explain the rating.

Rating Code:

R = Role Model: Consistently produce results that exceed performance expectations. Others describe as a leader and team player.

K = Key Contributor: Consistently produces results that meet or occasionally exceed performance expectations.
For new employees, performance reflects growth or progress in meeting expectations.

B = Below Standards: Results produced are below the performance expectations.

Performance Standards	Value-Added Result	Measures and Performance Zones	Rating
I Clinical Practice: Direct nursing care and/or supports direct nursing care using the nursing process for participants in clinical research, their families and significant others. Care requirements are determined by the scope of the study, clinical condition of the patient, requirements and clinical effects of research procedures.	Direct Nursing Care	**Measure:** Interaction with study participants, administration of research interventions, and provide nursing care in the context of research participation. Examples may include: Facilitate processing and handling (storage and shipping) of research specimens, educate research participants and family regarding study participation, monitor research participants and report potential adverse events to members of the research team, collect research data accurately in approved source documents within a designated time period; participation in clinical, unit, and/or protocol rounds; scheduling study related, tests, etc.). Disseminate information to medical and nursing staff related to ongoing and upcoming clinical trials. Prepares SAE reports for sponsor/study group and IRB submission. **Role Model:** Consistently completes all data requirements; data is always accurate and timely. 0-1 compliance reports per project, 0-1 late SAE submissions, consents timely and complete with correct version 100% of the time. Correct drug administered 100% of time. Drug label contains all required elements, drug reconciliation is always accurate. **Key Contributor:** Up to 3 justified deviations that do not affect patient safety. Data is always accurate, complete, and timely. Assures successful clinical trial data management. Correct drug administered 100% of time. Drug label contains all required elements, drug reconciliation is always accurate.	**R K B**

Competency Development Plan (circle the standard needing development above) and/or Comments:			
II. Study Management Dimension: Nursing management of clinical and research support activities to assure patient safety and address clinical needs, assure protocol integrity and accurate data collection.	Protocol development and implementation Communication: Screening and Recruitment: Data Management:	**Measure:** Participate in study development and identify clinical care implications during study development (such as staff competencies and resources, equipment, etc.). Examples may include: Participant in research participant recruitment, develop study specific materials for research participant education, provide nursing expertise to the research team during study development and implementation, coordinate & facilitate the collection of research specimens; contribute to the development of case report forms, participate in the setup of a study specific database. **Measure:** Facilitate accurate communication among research sites and within the research team **Measure:** Participate in screening potential research participants for eligibility and assist with participant recruitment. **Measure:** Collect data on research participant based on study endpoints, perform quality assurance activities to assure date integrity, and participate in the identification and reporting of research trends **Role Model:** Maintains effective protocol coordination, assures study requirements are met or exceeded and maintained through study completion, recruitment goals are exceeded; no unjustifiable protocol violations; receives positive comments on services. Demonstrates effort and develops strategies to improve recruitment or develop strategies when needed. Generates new ideas when studies slow to recruit. **Key Contributor:** Recruitment and goals are met, 1-3 justifiable protocol violations per trial.	**R K B**
Competency Development Plan (circle the standard needing development above) and/or Comments:			

III. Care Coordination and Continuity Dimension: Coordination of research and clinical activities to meet clinical needs, complete study requirements and manage linkage with referring and primary care providers and investigators.	Coordination of clinical research activities	**<u>Measure</u>: Collaborate, coordinate, and communicate with research participants as well as members of the interdisciplinary team.** Examples with the participants may include: facilitate scheduling and coordination of study procedures; communicate the impact of study procedures on the research participants; facilitate research participant inquiries and concerns. Examples with the interdisciplinary team may include: facilitate the education of the interdisciplinary team on the study requirements; collaborate with the interdisciplinary team to create and communicate a plan of care that allows for safe and effective collection of clinical research data; provide nursing leadership within the interdisciplinary team; coordinate referrals to appropriate interdisciplinary services outside the immediate research team; provide nursing expertise to community-based health care personnel related to study participation, participate in site visits and /or audits, provide input for study grant and budget development. Assists abstracting of protocols, researches data and prepares for PI review and submission to IRB. Function as liaison between site and sponsor/study groups. **Role Model:** Provides appropriate information to physicians. Alerts MD to any changes in status or situation, identifies and offers appropriate interventions. Provides immediate follow up with MD orders. Helps team improve performance. Takes initiative to complete extra assignments. Actively participates in program development/implementation of new initiatives. Provides and supports conflict resolution within the team. **Key Contributor:** Effective nurse - physician collaboration**.** Listens and communicates effectively with peers and supervisors. Offers to assist team with activities when own work completed. Accepts constructive suggestions from peers and supervisors and provides constructive input into program development.	**R K B**
Competency Development Plan (circle the standard needing development above) and/or Comments:			

IV. Human Subjects Protection Dimension: Facilitation of informed participation by diverse participants in clinical research.	Human subjects protection	**Measure:** Maintains applicable federal and institutional requirements for protection of human subjects and apply these principles to research participants. Examples may include: Maintains Human Subjects Training and Good Clinical Practice (GCP) Training; facilitate initial and ongoing informed consent / assent process; support research participants in defining reasons and goals for participating in a study; collaborate with the interdisciplinary team to address ethical conflicts; coordinate research activities to minimize subject risk; manage potential ethical and financial conflicts of interest for self; participate in the preparation of reports for appropriate regulatory and monitoring bodies / boards; protect research participant data in accordance with regulatory requirements **CITI/GCP current - YES NO** **Annual COI current - YES NO**	**R K B**
Competency Development Plan (circle the standard needing development above) and/or Comments:			

V. Contributing to the science dimension: Contribution as a research team member to the development of new ideas for study, explorations of innovations arising for clinical research findings to practice.	**Contributing to the science** **New Knowledge- Innovations and improvements**	**Measure:** Disseminate clinical expertise and best practices related to clinical research through presentations, publications and /or interactions with nursing colleagues. Examples may include: Disseminate clinical expertise and best practices related to clinical research through presentations, publications and / or interactions with nursing colleagues; serve as a resource to new investigators within your specialty area; participate in query and analysis of research data, if applicable; contribute to the generation of practice questions as a result of a new study procedure or intervention, if application; collaborate with the interdisciplinary team to potentially improve patient outcomes and accuracy of data collection; identify questions appropriate for clinical research as a result of study team participation Mentor junior staff and students participating as members of the research team, perform secondary data analysis to contribute to the development of new ideas, documentation of certification, maintaining of certification, attending conference and presenting follow up information at staff meeting, posters and/or presentation, contributing to authorship or the equivalent of, serving on a committee. **Role Model:** Two or more of the examples in the review year **Key Contributor:** One or more of the examples in the review year.	**R K B**

PART II. Core Value Behaviors

INSTRUCTIONS: Please circle the appropriate rating code, add comments at the end to individualize the document. Comments must be added for all reviews of below standards or role model to specifically explain the rating.

Rating Code:

R = Role Model: Consistently demonstrates Role Model level behaviors *in addition to* all Key Contributor level behaviors.
K = Key Contributor: Consistently demonstrates defined Key Contributor level Core Value Behaviors.
For new employees, performance reflects growth or progress in meeting expectations.
B = Below Standards: Does not consistently demonstrate Key Contributor Behaviors.

<table>
<tr><th>Performance Standards</th><th colspan="2">Measures and Performance Zones</th><th>Rating</th></tr>
<tr><td rowspan="2">I. Caring

Creates positive relationships with those served by putting them first in all interactions.
Effectively meets the needs of those served in a compassionate, responsive and courteous manner.</td><td colspan="2"><u>Measure</u>: Manager observation, employee self-assessment and other internal & external patient/customer feedback</td><td rowspan="2">R K B</td></tr>
<tr><td>Key Contributor:
Anticipates and meets the needs of those served by assuming responsibility for providing care and services in a professional, courteous and timely manner.
Introduces self, demonstrates courteous behavior by extending genuine words of concern, calling people by name, giving them their full attention & using appropriate body language.
Asks questions for clarity, listens carefully, provides appropriate information in a manner others can understand, & summarizes to check understanding.
Works to resolve and handle problems/concerns for those served.</td><td>Role Model:
Anticipates the needs of those served and consistently exceeds their expectations.
Excels in resolving difficult situations and restoring constructive relationships with those served.</td></tr>
<tr><td colspan="4">Comments with Development Plans:</td></tr>
<tr><td>II. Teamwork</td><td colspan="2"><u>Measure</u>: Manager observation, employee self-assessment and other internal & external patient/customer feedback including formal recognition programs.</td><td></td></tr>
</table>

Performance Standards	Measures and Performance Zones		Rating
Actively participates as a member of a team or department to get the work completed. Demonstrates flexibility and cooperation. Helps to remove obstacles for the team to reach goals.	**Key Contributor:** • Listens and involves others in team decisions or actions. Builds and maintains positive working relationships. • Works cooperatively with other team members, offers assistance, shares work credit, accepts and offers constructive feedback. • Demonstrates personal commitment to team and other staff, does not speak negatively about others, respects differences.	**Role Model:** • Pro-actively supports coworkers and other teams in developing a team approach to work or learning new skills. • Proposes ideas and develops new approaches to remove obstacles for team to reach goals. Volunteers to assist in implementing improvements. • Consistently maintains positive working relationships in the face of conflict. Assists others in resolving conflict. • Serves as source of positive motivation and encouragement for others.	**R K B**
Comments with Development Plans:			
III. Excellence Strives for the highest quality in all aspects of work performance. Learns and uses new information, skills and knowledge. Assumes responsibility for improving care/services.	**Measure:** Manager observation, employee self-assessment and other internal & external patient/customer feedback.		**R K B**
	Key Contributor: • Seeks to achieve the highest quality standards by following established procedures, accurately completing work in a timely manner, taking action to correct errors and notify others that may be affected. • Utilizes resources efficiently at all times. • Seeks to improve individual performance by demonstrating commitment to ongoing learning and gaining new knowledge and skills. Completes mandatory education, acquires and adapts to new job skills/technology as required, • Open to new ideas, seeks to understand change and adapts positively. • Demonstrates systems thinking by understanding the impact of their actions & responsibilities on others inside and outside of their department.	**Role Model:** • Consistently demonstrates high levels of performance. Assumes additional duties during difficult times i.e. crisis, turnover etc. • Proposes ideas and develops new approaches to improve care/service quality and productivity of job and department. • Consistently behaves as a lifelong-learner by learning, applying and integrating new knowledge and skills to improve service. Supports and assists others in developing their skills and improving their contributions. • Behaves as a systems thinker by demonstrating responsibility for their actions inside and outside of the department.	

<table>
<tr><th>Performance Standards</th><th colspan="2">Measures and Performance Zones</th><th>Rating</th></tr>
<tr><td colspan="4">Comments with Development Plans:</td></tr>
<tr><td>IV. Integrity

Consistently demonstrates actions which are professional, & responsible portraying trustworthiness and dependability</td><td colspan="2"><u>Measure</u>: Manager observation, employee self-assessment and other internal & external patient/customer feedback.</td><td rowspan="2">R K B</td></tr>
<tr><td>Key Contributor:
Includes complete and accurate information in everyday work performance.
Fulfills personal and professional commitments and promises.
Respects and maintains confidentiality of patients, customers and colleagues in all situations.
Uses sound judgment within scope of authority in decision making.
Demonstrates ethical and appropriate workplace behaviors.</td><td>Role Model:
Demonstrates conviction in articulating or doing the right thing in difficult or demanding situations even when it may be perceived negatively.</td></tr>
<tr><td colspan="4">Comments with Development Plans:</td></tr>
<tr><td>V. Leadership</td><td colspan="2"><u>Measure</u>: Manager observation, employee self-assessment and other internal & external patient/customer feedback.</td><td></td></tr>
</table>

Performance Standards	Measures and Performance Zones		Rating
Assumes responsibility for quality care and services and in all situations. Adapts positively to change.	**Key Contributor:** • Readily accepts responsibility for job duties, team and department service requirements. • Is self-directed and takes ownership to manage self and work including responsibility for actions and accountability for results. • Seeks to understand change, adapts and performs well in the changing environment.	**Role Model:** • Pro-actively supports and assists others in developing their skills and knowledge. Influences co-workers to demonstrate core values and to meet team, department and organizational goals. • Consistently exhibits conduct that serves as an example to others. • Acts as a positive change agent, supporting and influencing others to adapt to the changing environment.	**R K B**
Comments and Development Plans:			
VI. Pride Creates a positive impression in dress and manner. Serves as an ambassador for our health system.	**Measure:** Manager observation, employee self-assessment and other internal & external patient/customer feedback.		**R K B**
	Key Contributor: • Behaves in a dignified manner demonstrating respect for self and others in all aspects of performance. • Maintains a personal appearance that conveys confidence and professionalism, and demonstrates respect for the patients and customers we serve. • Serves as an ambassador for our health system by always speaking and behaving positively in and outside of the workplace.	**Role Model:** • Always behaves in a dignified manner in adverse situations. Seeks out and takes advantage of opportunities to share Christiana Care's Mission, Vision and Values and improve our image in the eyes of patients and other internal and external customers.	

Performance Standards	Measures and Performance Zones	Rating
Comments and Development Plans:		

PART III. Critical Skills (low volume, high risk)

INSTRUCTIONS: Check the box(es) that apply when completing the evaluation.
For age specific categories place N/A = not applicable to the specific age population if does not apply.

Critical Skills	Neonatal	Pediatric	Adolescent	Adult	Geriatric	Currently in Training	Yes – Performs Skills	No – Does Not Perform Skills

REVIEWER COMMENT SECTION:
(If the overall rating is Role Model or Below Standards, please explain the reason(s) for this rating below.)

EMPLOYEE COMMENT SECTION:

Performance Reviewed by:

_____ _____
Reviewer's Signature Date

_____ _____
Employee's Signature Date

APPENDIX F: CHECKLIST FOR SELECTING A CLINICAL TRIAL MANAGEMENT SYSTEM

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SYSTEM CAPABILITY	REQUIREMENT	DESIRABLE
Manage Sponsor Contracts, Services and Invoicing		
Manage Milestone Payments		
Build a Budget		
Build a Coverage Analysis grid to track study visits		
Create and Manage Subject Calendars Which Are Study Specific		
Provide Ability to Track Budgets and Actual Costs per Trial		
Provide Trial Statuses – PI, Pt, Documentation, Milestones		
Track 1572 Documentation such as CVs and Medical Licenses		
Demonstrate Work Load Assessment of Each Staff Member According to Trial Assignment		
Allow for Subject Tracking per Visit Completion		
Provide Check Off List of CRF Completion		
Provide Tracking of Study Drug		
Has Ability to Interface with Electronic IRB System		
Has Ability to Interface with Additional System Within Facility		
Provides interface to the Financial Management System		
Provides Interface to EMR		
Provides Interface to Scheduling System if Different Than Above		
Ad Hoc Reporting to Develop Reports with Output to Crystal Reporting, Excel or other System Requirement		
Available to Staff Remotely 24/7		
Support by Vendor for Implementation and Training		
Support by Vendor by Telephone once Implemented		
Provide Use of Various Coding Dictionaries or Creation of Data Dictionaries		
Concomitant Med Pick List		
Traceable Data Base Changes and Validation		
21 CFR Part 11 Compliant		
Electronically Signed Capability		

APPENDIX G: QUALITY ASSURANCE AUDIT CHECKLIST

Used with permission from Kandie Dempsey, Christiana Care Health System

Study Number: _____ **Case Number:** _____

Patient Name: _____ **Nurse/CRA Responsible:** _____

Auditing Nurse: _____

Was the chart audited within 24 hours of Nurse/CRA notification of audit?	Y	N	N/A

CONSENT

Was the consent the current IRB-approved version?	Y	N	N/A
Has the patient been re-consented?	Y	N	N/A
Are there copies on the chart?	Y	N	N/A
Was the informed consent signed and dated by the patient?	Y	N	N/A
Was consent signed prior to protocol entry?	Y	N	N/A
Are all of the blanks filled in?	Y	N	N/A
Was consent signed prior to protocol treatment?	Y	N	N/A
Is the consent date & time documented if protocol entry & treatment occurred on the same day?	Y	N	N/A
Are all required signatures present?	Y	N	N/A
Is the consent process documented?	Y	N	N/A
Is the Informed Consent Form completed & with the consent?	Y	N	N/A

ELIGIBILITY

Eligibility checklist completed?	Y	N	N/A
Was the 2 Nurse Verification check signed & dated?	Y	N	N/A
MD signature obtained & dated?	Y	N	N/A
Do all of the elements of eligibility have primary source documentation?	Y	N	N/A
➢ Are they completed within the required time frame?	Y	N	N/A
▪ Lab results?	Y	N	N/A
▪ Radiographic reports?	Y	N	N/A
▪ Pathology results?	Y	N	N/A

PROTOCOL TREATMENT

Was treatment provided as per protocol?	Y	N	N/A
Were there any dose modifications?	Y	N	N/A
➢ If so, were they done according to protocol?	Y	N	N/A
Did the patient receive radiation?	Y	N	N/A
➢ Is the prescription and treatment record on the chart?	Y	N	N/A
➢ If applicable, were treatment times recorded?	Y	N	N/A
➢ If a medication needed to be given prior to radiation, is it documented?	Y	N	N/A
Were the patient's Height, Weight and BSA recorded?	Y	N	N/A
Are there drug administration records for each cycle of chemotherapy?	Y	N	N/A

Was the 2 nurse verification completed on the Oral Prescription Form?	Y	N	N/A
Are there signed, dated and reconciled copies of drug diaries?	Y	N	N/A
Are there any **required** labs &/or radiographic scans for each cycle?	Y	N	N/A
➢ Are there copies on the chart?	Y	N	N/A
➢ Were they completed in the appropriate time frame?	Y	N	N/A
➢ Was there any toxicity noted within the labs?	Y	N	N/A
▪ If so, were they documented	Y	N	N/A
▪ Were they reported appropriately?	Y	N	N/A
Were there any **mandatory** Correlative Specimens or other **mandatory** Specimen Testings?	Y	N	N/A
Did the patient consent to have the **optional** Correlative Specimens collected?	Y	N	N/A
➢ Were they collected at the appropriate times?	Y	N	N/A
Were there any **mandatory** QOLs?	Y	N	N/A
➢ Were they submitted correctly/On-Time?	Y	N	N/A
Did the patient consent to complete the **optional** QOLs?	Y	N	N/A
➢ Were they submitted correctly/On-time?	Y	N	N/A
Was any non-protocol treatment given?	Y	N	N/A
➢ If so, was the non-protocol form completed?	Y	N	N/A

DEVIATIONS

Were there any deviations?	Y	N	N/A
➢ Was a deviation report completed and submitted to Lisa?	Y	N	N/A
▪ Is the report on the chart?	Y	N	N/A

DISEASE OUTCOME/RESPONSE

Was the Follow-Up process followed?	Y	N	N/A
➢ Is the Follow-Up Transfer Form completed and Up-To-Date?	Y	N	N/A
➢ Is a copy on the chart?	Y	N	N/A
Is the Follow-Up current?	Y	N	N/A
➢ Is there source documentation that corresponds with the dates of Follow-Up reports?	Y	N	N/A
Were the required exams, labs, radiographic reports, QOL & specimens completed in a timely fashion?	Y	N	N/A

***For CRA's only:**

- check with manager for Queries/Overdue Forms for studies not on RAVE

CREDIT

Auxiliary Doctor noted?	Y	N	N/A
Credit Checks completed?	Y	N	N/A
➢ Financial milestones checked?	Y	N	N/A
Was the Consent uploaded?	Y	N	N/A
Was there ever a Re-Consent needed?	Y	N	N/A
➢ Was it uploaded?	Y	N	N/A
Is the patient in Follow-Up?	Y	N	N/A
➢ Is there a Z – Arm assigned?	Y	N	N/A
➢ Is the completion date entered?	Y	N	N/A

OPEN FUNDING

Are the specimens or QOL submission dates entered or comments if not submitted?	Y	N	N/A

RAVE/DQP

Any overdue forms?	Y	N	N/A
Any active queries?	Y	N	N/A

DARF'S

Do the chart records agree with the DARF (PO & IV)?	Y	N	N/A

RADIATION ONCOLOGY

If there was a Radiation component, was the Radiation Communication Procedure Followed?	Y	N	N/A
➢ Was the Radiation Therapy Alert form completed appropriately?	Y	N	N/A

COMMENTS: