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LIBRARY OF RESOURCES:

CONDUCTING AND MANAGING CANCER CLINICAL TRIALS

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ASCO CENTRA
Center for Research & Analytics

OVERVIEW

This library of resources was compiled to centralize resources related to conducting and managing clinical trials. The resources are particularly helpful for physician investigators and research staff. A Task Force of the ASCO Research Community Forum, representing a range of community research stakeholder groups with a wealth of experience, compiled this list to help make it easier for research sites, physician investigators, and research staff find needed resources. Decisions to include resources were solely based on the Task Force's own go-to resources, consultation with colleagues, and an landscape review of available resources on these topics. Resources from commercial, for-profit entities are generally excluded from the library. The items listed are not necessarily endorsed by ASCO; they are listed based on the discretion and expertise of the Task Force.

This list is not exhaustive and will be updated periodically. Your feedback is welcomed! If you have ideas for content to add or edit, please email your suggestions to research@asco.org.

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Disclaimer: This library contains resources and templates that are provided as examples only for research programs to consider as they formulate their own resources. ASCO makes no warranties, expressed or implied, as to results obtained by individuals using the information and is not responsible for any action taken in reliance on the information contained herein.

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For more information contact research@asco.org.

Navigating the Library

These are the key categories covered in this library clinical trial resources. Click on each box to view that section's resources.

The library may also be navigated by utilizing the Table of Contents or your search function (typically CRTL + F on a keyboard). Additionally, you can jump back to the beginning of each section or the library Table of Contents by using the document bookmarks (accessible in PDF viewers).

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APPENDICES

I. Basic Requirements for Starting a Research Site

A variety of online resources are listed below with information about some of the basic considerations when building a clinical research site, including infrastructure, regulatory requirements, patient engagement, access to trials, and best practices. This list is not exhaustive and will be updated periodically.

This section includes the following topics:

A. Building an Effective Research Program
B. Partnerships
C. Marketing your Research Program
D. Building Program Infrastructure
E. Mission Statements and Policies
F. Creating a Culture of Research
G. Mentorship
H. Good Clinical Research Practices
   i. ICH GCP References
I. Building a Clinical Trial Portfolio
J. Standard Operating Procedures

A. Building an Effective Research Program

Clinical research moves medicine forward and is a necessary part of bringing any new therapy, device, or procedure into routine medical care. However, it can be costly and convoluted. Building an effective research program requires establishment of a clinical trials infrastructure, financial oversight and a sustainable qualified research team. Although the physicians are vital to creating a research culture and enrolling patients on trials, nonphysician staff-including nurses, data managers, clinical research associates, pharmacy staff and staff responsible for reimbursement are imperative to the overall success of the program.

- Copur MS: How to Build a Clinical Trial Infrastructure in the Community Oncology Setting. The ASCO Post. 2018.
- A Manual for Participants in Clinical Trials of Investigational Agents Sponsored by DCTC, NCI. This manual from the Division of Cancer Treatment and Diagnosis (DCTD), National Cancer Institute (NCI) includes policies and procedures related to various elements of the development of new investigational agents.
- Cancer Clinical Trials Basics. This online module, produced by the National Cancer Institute, provides introductory-level information regarding cancer clinical trials.
- Conducting Clinical Trials. Information from the National Cancer Institute is available for investigators, including tools for managing trials, registration/reporting and ensuring patient safety.
- Association of Clinical Research Professionals: Core Competencies for Clinical Research Coordinators (CRCs).
- Association of Clinical Research Professionals. Functional Competency Guidelines for Principal and Sub Investigators.

- A Handbook for Clinical Investigators Conducting Therapeutic Clinical Trials Supported by CTEP, DCTD, NCI. This resource from the National Cancer Institute covers policies and implementing procedures for conducting clinical trials sponsored by the Division of Cancer Treatment and Diagnosis (DCTD), National Cancer Institute (NCI).
- Minimizing Research Delays: Identifying Successful Strategies to Keep a Clinical Trial Moving Forward. J Oncol Pract. 2007; 3(6):306-307. In this article, representatives from practices awarded the 2007 ASCO Clinical Trials Participation Awards discuss strategies they have implemented to keep clinical trials on track.
- National Cancer Institute. Resources for Researchers. This directory of resources provides. National Cancer Institute supported tools and services for cancer researchers.
- Association of Clinical Research Professionals Webinar Replay: Drug Development Process: A Review of ICH E8 (Free to ACRP members). Content includes principles and practices for the conduct of clinical trials and overall development strategy, evaluation of international trial data, and overview of ICH guidelines pertinent to clinical trials.
- The Elements of Success, Conducting Cancer Clinical Trial: A Guide. This document is intended as a resource to provide general information on the conduct of clinical trials for new and prospective clinical trial investigators and sites.
- ASCO Exemplary Attributes Series: An ongoing article series in the Journal of Oncology Practice provides practical information on how to implement the GCP guidelines and exemplary attributes.
    - Zon R, Meropol N, Catalano R, et al. Minimum Standards and Exemplary Attributes of Clinical Trial Sites. J Clin Oncol. 2008; 26(15):2562-2567. The seminal manuscript in the ASCO Exemplary Attributes series describes the minimum requirements for conducting quality clinical trials and the attributes of an exemplary site.
    - Baer AR, Cohen G, Smith DA, et al. Implementing Clinical Trials: a Review of the Attributes of Exemplary Clinical Trial Sites. J Oncol Pract. 2010; 6(6):328-30. Part 1 in a two-part series, this article outlines the following exemplary attributes, diversification of the clinical trial mix, high accrual activity, participation in the clinical trial development process, and maintenance of high educational standards.
    - Zon R, Cohen G, Smith DA, et al. Part 2: Implementing Clinical Trials: a Review of the Attributes of Exemplary Clinical Trial Sites. J Oncol Pract. 2011; 7(1):61-4. Part 2 in a two-part series, this article outlines the following exemplary attributes, quality assurance, multidisciplinary involvement in the clinical trial process, and clinical trial awareness programs.
    - Enhancing Oncologist Participation in Research. J Oncol Pract. 2009; 5(6):309-311. This article, from the ASCO Exemplary Attributes Series, offers strategies to increase oncology engagement in research.
- Human Subjects Research. This webpage, produced by the National Institutes of Health, provides the user with access to ethical codes and standards such as the Declaration of Helsinki, Belmont Report, and International Conference on Harmonization Guideline for Good Clinical Practice.
- National Institutes of Health (NIH). Standards for Clinical Research within the NIH Intramural Research Program.

- International Clinical Trials Workshops through ASCO. These workshops support cancer researchers in low- and middle-income countries in developing research skills.
- Various projects from the Clinical Trials Transformation Initiative related to clinical trials.
- How to start a clinical research site. PharmaTimes. 2018.

B. Partnerships

A strong partnership is commonly at the heart of a successful clinical research program. The resources below provide insights into the benefits and how to establish effective 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, 2013. 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.
- Copur MS, Ramaekers R, Gonen M, et al. Impact of the National Cancer Institute Community Cancer Centers Program on Clinical Trial and Related Activities at a Community Cancer Center in Rural Nebraska. J Oncol Pract. 2016; 12(1):67-8, e44-51.
- Copur MS, Gulzow M, Zhou Y, et al. Impact of National Cancer Institute (NCI) Community Cancer Centers Program (NCCCP) and NCI Community Oncology Research Program (NCORP) on Clinical Trial (CT) Activities in a Community Cancer Center. J Clin Oncol. 2018; 36(15_suppl), e18500-e18500.

C. Marketing your Research Program

Marketing your research program involves sharing it with a wider audience to make it more visible. This can be helpful in the initial steps of research, particularly when actively recruiting for participants to enroll in your clinical trials. Generating awareness of clinical trial enrollment can help increase interest and ultimately assist in helping you to reach your enrollment goals.

- Keck School of Medicine of University of South Carolina. How and Why to Promote your Research.
- BioMed Central. 10 Tips for Promoting your Research Online.
- Enago Academy. Promote your Research with these 7 Simple Techniques!

D. Building Program Infrastructure

Refer to the below resources for information on the elements and steps involved in establishing program infrastructure.

- Baer A, Bechar N, Cohen G, and Devine S. Basic Steps to Building a Research Program. J Oncol Pract. 2010; 6(1):45-47. This article from the ASCO Exemplary Attributes series provides practical advice for investigators on research program financial oversight and how to sustain a qualified team.
- ASCO Building a Research Program At-a-Glance Summary. This ASCO resource provides an overview of the key tips, takeaways, and considerations for building a research program.
- U.S. Food and Drug Administration. Computerized Systems used in Clinical Trials. 1999.
- Including Clinical Trials into your Practice: This online module, produced by the National Cancer Institute, targets healthcare professionals with advanced knowledge of cancer clinical trials who want to better incorporate trials into their practice.
- Ford E, Jenkins V, Fallowfield L, et al. Clinicians' attitudes towards clinical trials of cancer therapy. Brit J Cancer. 2011; 104:1535–1543.
- Copur MS. How to Build a Clinical Trial Infrastructure in the Community Oncology Setting. The ASCO Post. 2018.

E. Mission Statements and Policies

(e.g., participation in research, selection of clinical trials, clinical trial portfolio and diversity, etc.)

- Enhancing Clinical Trial Awareness and Outreach. J Oncol Pract. 2009; 5(4):205-207. This article from the ASCO exemplary attributes series discusses clinical trial education programs, diversification of trial mix, multidisciplinary involvement, and high accrual.
- Zaren HA, Nair S, Go RS, et al. Early-Phase Clinical Trials in The Community: Results From the National Cancer Institute Community Cancer Centers Program Early-Phase Working Group Baseline Assessment. J Oncol Pract. 2013; 9(2):e55-e61. This article discusses how community cancer centers can conduct early-phase trials based on findings from a National Cancer Institute Community Cancer Centers Program Early-Phase Working Group baseline assessment.
- Identifying and Selecting a Clinical Trial for Your Practice. J Oncol Pract. 2008; 4(1):27-28. Representatives of three practices recognized by the 2007 Clinical Trials Participation Awards shared their strategies for identifying and selecting trials in this article.

F. 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. Clin Trials. 2015; 12(3):246-256. 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. Contemp Clin Trials. 2007 ; 28(4):557-562.

G. 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. J Cancer Educ. 2019; 34(4):629-637. 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? Clin J Oncol Nurs. 2018; 22(1):120.

H. Good Clinical Research 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, to ensure compliance with GCP standards developed by various entities (i.e., International Code of Harmonisation [ICH] E6 GCP Guidance, U.S. Food and Drug Administration, Clinical Trials Transformation Initiative [CTTI], and TransCelerate BioPharma Inc.). For specific resources on GCP training, refer to section **i. Good Clinical Practice Training**.

- Baer AR, Hajovsky J, Zon R. Achieving Exemplary Attributes with AccrualNet. J Oncol Pract. 2011; 7(6):e40-1. This article, from the ASCO Exemplary Attributes series, highlights how AccrualNet can be used to achieve the seven attributes of exemplary clinical research sites. For more information on the attributes, refer to the ASCO exemplary attributes statement and subsequent series.
- Ethics and Human Subject Protection: A Comprehensive Intro. (Free for ACRP members) This course from the Association of Clinical Research Professionals provides in-depth training on the history and importance of ethical conduct in clinical trials involving human subjects.
- Good Clinical Practice Research Guidelines Reviewed, Emphasis Given to Responsibilities of Investigators: Second Article in a Series. J Oncol Pract. 2008; 4(5):233-235. This article from the ASCO Exemplary Attributes series describes Good Clinical Practice guidelines and places them into historical perspective before specific aspects of implementing the guidelines—through the use of trained research professionals and well-written Standard Operating Procedures (SOPs)—are discussed.
- Rare Disease Clinical Research Network. Good Clinical Practice and Federal Code of Regulations.
- Intro to Good Clinical Practice. (Free to ACRP members) This course from the Association of Clinical Research Professionals covers the basics and key considerations of Good Clinical

Practice, including review of the guidelines of the International Council for Harmonisation's Good Clinical Practice and investigator roles and responsibilities.

- Denicoff AM, McCaskill-Stevens W, Grubbs S, et al. The National Cancer Institute–American Society of Clinical Oncology Cancer Trial Accrual Symposium: Summary and Recommendations. J Oncology Pract. 2013 ;9(6):267-276. This article provides a summary of and recommendations for the future from the 2010 National Cancer Institute and American Society of Clinical Oncology co-sponsored Cancer Trial Accrual Symposium.
- Arango J, Chuck T, Ellenberg S, et al. Good Clinical Practice Training: Identifying Key Elements and Strategies for Increasing Training Efficiency. Ther Innov Regul Sci. 2016; 50(4):480-486.
- TransCelerate Recommendations. Site qualification and training. TransCelerate BioPharma, Inc.

i. ICH GCP References

- E6(R2) Good Clinical Practice: Integrated Addendum to ICH E6(R1) Guidance for Industry. U.S. Food and Drug Administration. 2018.
- ICH Clinical Safety Data Management: Definitions and Standards for Expedited Reporting E2A. International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use. 1994
- General Considerations for Clinical Trials (E8). International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use. 1998.

I. Building a Clinical Trial Portfolio

View clinical trial databases and listings via the following resources.

- Clinicaltrials.gov. ClinicalTrials.gov is a registry and results database of publicly and privately supported clinical studies of human participants conducted around the world.
- U.S. Department of Health and Human Services Listing of Clinical Trial Registries
- US Oncology. Learn more, find a clinical trial, or join the US Oncology Network of oncology sites.

J. Standard Operating Procedures

(e.g., preparing, maintaining, and training on Standard Operating Procedures [SOPs])

- NRG Oncology Manual of Operations and Standard Operating Procedures for the San Francisco Biospecimen Bank. (Direct file download) This resource details the NRG Oncology Biospecimen Bank's operations and includes helpful templates and sample documents.
- Draft SOPs documents on a wide range of topics from Dana-Farber/Harvard Cancer Center. This document library offers draft documents, guidance, and policies around SOPs.
- Goldfarb N. Something for Everyone: Standard Operating Procedure Products for the Investigative Site. J Clin Res Best Pract. 2005; 1(4). This article discusses various commercial products for investigative site SOPs.
- Duke Global Health Institute SOP Study Termination Visit. This resource provides SOPs, which were originally developed for AIDS clinical trials, but many of which can be modified and extrapolated to meet oncology research trial needs.

II. Clinical Trial Operations

Resources are listed below for some of the administrative considerations for a research program, including site requirements and responsibilities, investigator and staff roles and responsibilities, budgeting and billing, and administrative best practices.

This section includes the following topics:

A. Investigative Site Requirements and Responsibilities

(e.g., Exemplary Attributes of Clinical Research Sites)

- E6(R2) Good Clinical Practice. Integrated Addendum to ICH E6(R1) Guidance for Industry. U.S. Food and Drug Administration 2018.
- Zon R, Meropol N, Catalano R, et al. Minimum Standards and Exemplary Attributes of Clinical Trial Sites. J Clin Oncol. 2008; 26(15):2562-2567. The seminal manuscript in the ASCO Exemplary Attributes series describes the minimum requirements for conducting quality clinical trials and the attributes of an exemplary site.
- Baer AR, Cohen G, Smith DA, et al. Implementing Clinical Trials: A Review of the Attributes of Exemplary Clinical Trial Sites. J Oncol Pract. 2010; 6(6):328-30. Part 1 in a two-part series, this article outlines the following exemplary attributes, diversification of the clinical trial mix, high

accrual activity, participation in the clinical trial development process, and maintenance of high educational standards.

- Zon R, Cohen G, Smith DA, et al. Part 2: Implementing Clinical Trials: a Review of the Attributes of Exemplary Clinical Trial Sites. J Oncol Pract. 2011; 7(1):61-4. Part 2 in a two-part series, this article outlines the following exemplary attributes, quality assurance, multidisciplinary involvement in the clinical trial process, and clinical trial awareness programs.
- Quality Assurance and Educational Standards for Clinical Trial Sites. J Oncol Pract. 2008; 4(6):280-282. This article, which builds on the ASCO Exemplary Attributes series, discusses how quality assurance and formal maintenance of high educational standards contribute to optimal site function.
- Zaren HA, Nair S, Go RS, et al. Early-Phase Clinical Trials in The Community: Results From the National Cancer Institute Community Cancer Centers Program Early-Phase Working Group Baseline Assessment. J Oncol Pract. 2013; 9(2):e55-e61. This article discusses how community cancer centers can conduct early-phase trials based on findings from a National Cancer Institute Community Cancer Centers Program Early-Phase Working Group baseline assessment.
- Identifying and Selecting a Clinical Trial for Your Practice. J Oncol Pract. 2008; 4(1):27-28. Representatives of three practices recognized by the 2007 Clinical Trials Participation Awards shared their strategies for identifying and selecting trials in this article.
- American Society of Clinical Oncology policy statement: oversight of clinical research. J Clin Oncol. 2003; 21(12):2377-2386.
- Refer to **I. Basic Requirements for Starting a Research Site** for more information on how to start a research site.

B. Investigator Roles and Responsibilities

(e.g., investigators roles and responsibilities, oversight, qualifications, credentialing, training, licensure, physician engagement, multidisciplinary team involvement) Refer to the National Cancer Institute Handbook for Clinical Investigators Conducting Therapeutic Clinical Trials Supported by CTEP, DCTD, NCI for NCI-specific policies and procedures.

- U.S. Food and Drug Administration. Form FDA 1572. (Direct file download)
- Baer AR, Devine S, Beardmore CD, et al. Clinical Investigator Responsibilities. J Oncol Pract. 2011: 7(2):124-8. This article from the ASCO Exemplary Attributes series discusses select investigator roles and provides practical advice on how to promote compliance in practice.
- Delegation of Tasks for Clinical Research. (Direct file download) This document from Dana-Farber/Harvard Cancer Center defines the standard research tasks delegated to investigators and each research staff member.
- Investigator Responsibilities. (Free to ACRP members) This Association of Clinical Research Professionals online learning course covers clinical investigator responsibilities and expectations identified by U.S. Food and Drug Administration guidance and International Council for Harmonisation guidelines.
- Baer AR, Zon R, Devine S, Lyss AP. The Clinical Research Team. J Oncol Pract. 2011; 7(3):188-92. This article from the ASCO Exemplary Attributes series offers strategies on developing and maintaining an exemplary research team.

- Saleh M and Naik G. So You Want to Be a Principal Investigator. J Oncol Pract. 2018; 14(6):e384-e392. This article addresses investigator responsibilities and the increasing need for structured investigator training.
- National Cancer Institute Guidelines for Investigators: Adverse Event Reporting Requirements for DCTD (CTEP and CIP) and DCP INDs and IDEs.

C. Conflict of Interest in Research

(e.g., regulations, financial conflicts)

- Korenman SG. Teaching the Responsible Conduct of Research in Humans (RCRH). Chapter 4 of this online book, Conflict of Interest, provides information, resources, considerations, and case studies to explain the role of conflict of interest in research.
- National Institutes of Health. Regulation on Financial Conflict of Interest.
- U.S. Department of Health and Human Services: Guidance on Financial Conflict of Interest. 2004.
- Open Payments, maintained by the Centers for Medicare and Medicaid Services, is a publicly accessible national disclosure program that provides information on financial relationships between applicable manufacturers and group purchasing organizations and health care providers.

D. Research Integrity and Scientific Misconduct Policies and Procedures

(i.e., U.S. governmental guidance and policies)

- U.S. Department of Health and Human Services Office of Research Integrity Introduction to Responsible Conduct of Research. This resource provides a comprehensive overview of the basic rules for responsible research.
- Federal Research Misconduct Policy. The policy from the U.S. Department of Health and Human Services Office of Research Integrity establishes the scope of the federal government's interest in the accuracy and reliability of the research record and the processes involved in its development. It consists of a definition of research misconduct and basic guidelines for the response of federal agencies and research institutions to allegations of research misconduct.
- Research Integrity Policy & Guidance. This National Institutes of Health resources provides a definition of research misconduct.

E. Research Staff Roles, Responsibilities, and Management

(e.g., staff roles and responsibilities, oversight, qualifications, job descriptions, core competencies, training requirements and maintenance, credentialing, orientation, workload assessment, performance)

- Society of Clinical Research Associates Certification develops clinical research professionals' knowledge understanding and application of international and federal regulations and established ethical principles in the conduct of clinical trials.

i. Organization Charts

Refer to the following resource for sample organizational charts to facilitate institutional organization.

- 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.

ii. 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 teamwork.

- Larkin ME, Blumenthal K, Richards D, et al. Collaborative Staffing Models for Multiple Sites. Applied Clinical Trials. 2011.
- Nancarrow SA, Booth A, Ariss S, et al. Ten Principles of Good Interdisciplinary Teamwork. *Hum Resour Health*. 2013; 11(19):1-11.
- 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. Clin Transl Sci. 2012; 5(6):470-475.
- Bishop P, Camblos L. The Value of Empowered CRAs in Rare Disease Studies. Applied Clinical Trials. 2017.
- Kee AN. Investigator Responsibilities for Clinical Research Studies: Proper Staffing Can Ensure an Investigator is Compliant. *J Med Pract Manag.* 2011; 26:245-247.

iii. 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.

- **Overview of Clinical Trial Research Staff Positions (Table 1).** *American Society of Clinical Oncology Research Community Forum Toolkit: The Business of Clinical Trials - Optimizing Clinical Trial Sites and Implementing Best Practices*. Alexandria, VA; American Society of Clinical Oncology; 2018.

iv. 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.
- 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. J Genet Couns. 2016; 25(4):644-648 – (Table 1).
- Nursing at the National Institutes of Health Clinical Center. Career Ladder. National Institutes of Health Clinical Center 2017.
- Framework for Career Ladder Program (Table 1) - Ko YK, Yu S. Clinical Ladder Program Implementation. A Project Guide. J Nurs Adm. 2014; 44(11):612-616.
- Warman G, Williams F, Herrero A, et al. The Design and Redesign of a Clinical Ladder Program. Thinking Big and Overcoming Challenges. J Nurses Prof Dev. 2016; 32(6):e1-e7 (Table 1).
- Advancing From Within: The Value of Clinical Ladders. American Association for Respiratory Care.
- Andrew N. Clinical Imprinting: The Impact of Early Clinical Learning on Career Long Professional Development in Nursing. Nurse Educ Pract. 2013; 13(3):161-164.
- Smailes P, Bookless H, Blumenauer C. Clinical Research Nurse Career Advancement Using Clinical Ladder Programs. Clin Res. 2017; 31(6).
- 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). Acad Radiol. 2010; 17(11):1449-1454.
- Warman G, Williams F, Herrero A, et al. The Design and Redesign of a Clinical Ladder Program: Thinking Big and Overcoming Challenges. J Nurses Prof Dev. 2016; 32(6):e1-e7.
- Keenan C: Struggling to Keep Entry-Level Staff Engaged? Try a Performance-Based Career Ladder. The Advisory Board Company: Care Transformation Center Blog. 2017.

v. Staff Retention

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 and identify strategies to retain high-performing staff.

- 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. J Consul Clin Psych. 2009; 77(2):270-280.
- Henderson L. Salary and Satisfaction. Applied Clinical Trials. 2017; 26(12).
- Henderson L. Catch (& Keep) a Rising Star: Clinical Research Talent Trends. Applied Clinical Trials. 2018; 27(3).
- Katzenbach JR, Smith DK. The Discipline of Teams. *Harv Bus Rev.* 1993; 71(2):111-120.

vi. 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.

- 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. J Oncol Pract. 2016 ;12(5):e536-547.
- Good MJ, Lubejko B, Humphries K, et al. Measuring Clinical Trial–Associated Workload in a Community Clinical Oncology Program. J Oncol Pract. 2013; 9(4):211-215.
- Smuck B, Bettello P, Berghout K, et al. Ontario Protocol Assessment Level: Clinical Trial Complexity Rating Tool for Workload Planning in Oncology Trials. J Oncol Pract. 2011; 7(2):80-84.
- Fowler DR, Thomas CJ. Protocol Acuity Rating Scoring as a Rational Approach to Clinical Research Management. Research Practitioner. 2003; 4(2):64-71.
- National Cancer Institute Consortia Webinar. Assessing Clinical Trial Associated Workload. 2018.
- National Cancer Institute 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. J Natl Compr Canc Netw. 2011; 9(11).

F. 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. There are many organizations that offers training on clinical trials and good clinical practice and the resources listed below provide helpful guidance on equipping your team for long-term success. **Appendix D** details a research nurse coordinator training and orientation tool to help staff understand good clinical practice and the conduct of research. The list provides examples only, it does not indicate endorsement from ASCO.

- Baer AR, Zon R, Devine S, et al. Attributes of Exemplary Research: The Clinical Research Team. J Oncol Pract. 2011; 7(3):188-192. See Training Log Examples - Figures 2 and 3.
- Oncology Nursing Society. 2016 Oncology Clinical Trials Nurse Competencies.
- Harmonized Core Competency Framework. Joint Task Force for Clinical Trial Competency. 2017.
- 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.
- U.S. Food and Drug Administration Clinical Investigator Training Course, which is periodically offered in-person, provides information on the scientific background and practical methodology needed for conducting clinical trials.
- The ASCO eLearning course collection, Fundamentals of Clinical Trials, is aimed at familiarizing new investigators with designing and conducting clinical research. Topics addressed include research design and methodology, regulatory and legal issues, data management, ethics, statistics, research teams, exemplary clinical trials sites, promotion of clinical trials, and informed consent.
- Entities Providing GCP and Human Subjects Protection Training:
    - The Collaborative Institutional Training Initiative Program offers paid online courses covering key regulatory and ethical areas, including Good Clinical Practice Training. Browse the catalogue.

i. Good Clinical Practice Training

Good Clinical Practice (GCP) training covers several topic areas related to ethical and scientific quality standards for designing, conducting, recording and reporting trials, to ensure compliance with GCP standards developed by FDA and other entities (i.e., ICH E6 Guidance, U.S. Food and Drug Administration, Clinical Trials Transformation Initiative [CTTI], and TransCelerate BioPharma, Inc.)

- Collaborative Institutional Training Initiative Good Clinical Practice (GCP) Training for Investigators.
- TransCelerate Biopharma Inc. Minimum Criteria for ICH E6 GCP Investigator Site Personnel Training.

G. Clinical Trial Operations/Processes

(e.g., tips for managing multiple sponsors and trials; internal quality assurance program; external inspections, auditing, and monitoring; biospecimen research infrastructure; Protocol Review and Monitoring Committee)

- Clinical Research Site Infrastructure and Efficiency. This article from the ASCO Exemplary Attributes series discusses infrastructure improvements that promote efficiency and provides examples of effective practices implemented at research sites.
- Clinical Trial Monitoring Competency Framework. This document from the Association of Clinical Research Professionals outlines the necessary knowledge, skills, and abilities for clinical trial monitors.
- Baer AR, Smith M, Bendell JC. Donating Tissue for Research: Patient and Provider Perspectives. J Oncol Pract. 2011; 7(5):334-337. This resource from the ASCO exemplary attributes series illustrates common patient and provider concerns about donating tissue for the purpose of research. The article discusses best practices and provides answers to common patient questions.

- National Cancer Institute. Guidelines for Auditing Clinical Trials for the NCI National Clinical Trials Network (NCTN, CCOP, and NCORP).
- Online Educational Videos. These online videos, developed by the Office of Human Research Protection (OHRP), cover a range of topics including: "General Informed Consent Requirements," "Institutional Review Board (IRB) Membership," "Research Use of Human Biological Specimens and Other Private Information," and "Reviewing and Reporting Unanticipated Problems and Adverse Events."
- U.S. Food and Drug Administration Guidance. Oversight of Clinical Investigations – A Risk-Based Approach to Monitoring. This guidance provides information to support development of risk-based monitoring strategies and plans for investigational studies of medical products. (2013).
- Refer to section **G. Drug Accountability, Storage, Dispensing and Return** for information and resources related to managing study drug(s).

i. 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.

ii. 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.

iii. 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. J Clin Oncol. 2016; 34(31):3796-3802.

H. Regulations

(i.e., U.S. federal regulations)

- U.S. Food and Drug Administration Regulations Relating to Good Clinical Practice and Clinical Trials. This listing also includes links to publications that contributed to the development of the FDA's regulations.
- Society of Clinical Research Associates Sponsored FDA Clinical Trial Requirements Regulations, Compliance, and GCP Conferences. These paid conferences offer continuing educations credits.

I. Electronic Medical Records Policies and Procedures

(e.g., requirements and processes)

- U.S. Food and Drug Administration Use of Electronic Health Record Data in Clinical Investigations Guidance for Industry. 2018.
- Laws, Regulation, and Policy. HealthIT.gov provides an overview of health IT related legislation and regulations.

J. Privacy

(e.g., HIPAA, privacy, confidentiality, and compliance related to participants, trials, and sponsors)

- Department of Health and Human Services Health Information Privacy the Privacy Rule and related rules and information.
- Privacy, Security, and HIPAA. HealthIT.gov offers information and resources to help researchers ensure the privacy and security of health and patient information.
- National Institutes of Health. Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule.
- Understanding HIPAA privacy in research. This resource from the U.S. Department of Health and Human Services explains each element of the HIPAA Privacy Rule.
- Stanford University Human Research Protection Program Policy Manual (Direct file download).

K. Budget Management and Billing

Resources in this section address the financial management of a research program, including developing program budgets, sample budgets, patient billing procedures, and insurance coverage.

- University of California San Francisco Sample Budget for Clinical Trials.
- Budget Preparation. This resource from Ohio State University Center for Clinical and Translational Science provides high-level considerations for budget preparation.

- Cost-Neutral Clinical Research Enterprise. J Oncol Pract. 2009; 5(2):76-79. This article from the ASCO exemplary attributes series addresses the challenge of creating a research program that at minimum will be self-supporting. Two attributes of a cost-neutral clinical research enterprise are diversification of trial mix and high accrual activity.
- Industry Clinical Trials Budgeting and Financial Management. This presentation from the University of California San Francisco provides an overview of the financial aspects and considerations of conducting clinical trials.
- Farrell B, Kenyon S, Shakur H. Managing Clinical Trials. Trials. 2010; 11(78). This article discusses the need for standard trial management guidelines and evaluation methods.
- Lee K. How to Keep the Project on Budget in the Clinical Trial Study. This article, from Cytel Inc., covers the different elements involved in the biometrics budgeting process of clinical trials.
- Making Research Dollars Stretch for Community Practices. J Oncol Pract. 2008; 4(2):81-82. Several representatives from practices who received the 2007 ASCO Clinical Trials Participation Awards share strategies on how their sites handle clinical trial funding issues.

i. Finance and Site Development/Growth

Review the links below to learn about return on investment in clinical cancer research and how to develop an investigator site budget.

- Fricker J. Study Estimates Economic Returns from UK Cancer Research. Lancet Oncol. 2014; 15(8):e314. 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. J Oncol Pract. 2007; 3(2):94-97. Article discussed site budget issues and the importance of covering all costs.

ii. Research Patient Billing Procedures

(e.g., U.S. policies on patient billing, information for patients)

- Centers for Medicare and Medicaid Services National Coverage Determination for Routine Costs in Clinical Trials.
- ASCO Resources on Insurance Coverage of Clinical Trials include information on the Affordable Care Act Requirements for private insurance coverage, Medicare coverage, Medicaid coverage, and relevant state laws and cooperative agreements.
- Form to Demonstrate that a Trial Meets Statutory Requirements. ASCO has created an attestation form based on the law that can help demonstrate that the trial and patient's circumstances meet the coverage requirements.
- ASCO Insurance Coverage At-a-Glance Summary. This ASCO Research Community Forum resource provides key tips, considerations, and strategies to assist sites with insurance coverage of clinical trials.
- Health Insurance Coverage and Clinical Trials. This resource for patients from Cancer.net provides an overview of and considerations for insurance coverage of clinical trial participation include relevant legislation and related resources.

iii. 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 online. A summary of key resources is also available.
- 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**.** J Oncol Pract*.* 2017; 13(6):395-400.
- 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. J Clin Res Best Pract. 2010; 6(3):2-5.
- Willenberg KM. Managing Clinical Trials-Frustration or Bliss? J Oncol Manag. 2004; 13(6):24-26.

III. Study Start-up

Resources listed below cover the fundamental elements of study activation, initiating a clinical trial at a research site.

This section includes the following topics:

A. Protocol Handling
B. Study Activation
   i. Qualifying Clinical Trial Sites
C. Compliance and Regulations
D. Submitting a New Study Application to an Institutional Review Board
E. Protocol Review and Monitoring Committee
F. Confidentiality Agreement

A. Protocol Handling

(i.e., review for feasibility)

- Assessing Protocol Feasibility. This resource from Ohio State University Center for Clinical and Translational Science provides considerations to facilitate assessing study protocols for feasibility.
- Protocol Feasibility Analysis. This presentation from Oregon Health & Science University provides an overview, key questions, and case studies to facilitate assessing protocol feasibility.
- Clinical Trial Feasibility Checklist (Direct file download) This tool from University of California San Francisco outlines key questions and considerations to help decide protocol feasibility.

B. Study Activation

(e.g., industry pre-study site visits, site initiation meetings and visits)

- Study Activation Form from the Stanford University School of Medicine Research Management Group
- National Cancer Institute Division of Cancer Prevention Clinical Study Initiation Visit Report (Direct file download)
- Refer to **F. Monitoring by Sponsor/Contract Research Organization** for more information on sponsor and contract research organization site visits.

i. 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 to reduce administrative burden on clinical trials sites and expedite clinical trial accrual.

- 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. J Oncol Pract. 2016; 12(1):63-64, e23-35.
- Johnston SC, Austin CP, Lewis-Hall F. Voluntary Site Accreditation — Improving the Execution of Multicenter Clinical Trials. N Engl J Med. 2017; ;377:1414-1415.
- Johnston SC, Lewis-Hall F, Bajpai A, et al. It's Time to Harmonize Clinical Trial Site Standards. National Academy of Medicine. 2017.
- Koski G, Kennedy L, Tobin MF, et al. Accreditation of Clinical Research Sites - Moving Forward. N Engl J Med. 2018; ;379(5):405-407.

C. Compliance and Regulations

(e.g., Completing an FDA Form 1572; federally required registering of trials on websites)

- Form FDA 1572. Get it Right the First time (Free to ACRP members) This course from the Association of Clinical Research Professionals explains the FDA form 1572 and is geared towards staff completing 1572s and sponsors instructing sites and reviewing forms.
- U.S. Food and Drug Administration Instructions for Filling Out Form FDA 1572 (Direct file download)

D. Submitting a New Study Application to an Institutional Review Board

(e.g., process overview, U.S. guidance)

- U.S. Food and Drug Administration IRB Responsibilities for Reviewing the Qualifications of Investigators, Adequacy of Research Sites, and the Determination of Whether an IND/IDE is Needed Guidance for IRBs, Clinical Investigators, and Sponsors (Aug 2013)
- Submitting a Study for Initial Review. The National Cancer Institute Central Institutional Review Board provides this guide as an overview of the initial review process.

- For more resources related to Institutional Review Boards, see **C. Institutional Review Board (IRB) Review Procedures**.

E. Protocol Review and Monitoring Committee

- Essential Elements of a Data Safety and Monitoring Plan for Clinical Trials Funded by the NCI. This resource from the National Cancer Institute identifies the essential elements of an effective data and safety monitoring plan for clinical trials.

F. Confidentiality Agreement

- Accelerated Research Agreements Accelerated Confidentiality Disclosure Agreement
- Non-Disclosure Agreements. This resource from the Standard Medicine Research Management Group provides an overview and helpful resources to facilitate the confidentiality agreement process.
- Memorial Sloan Kettering Cancer Center Standard Clinical Trial Agreement.

IV. Management of Activated Trials

The resources listed below provide tools and information on effectively managing a research site, including the contracting, institutional review board, documentation, and adverse events reporting processes and procedures.

This section includes the following topics:

A. Study-Specific Protocols, Procedures, and Requirements
B. Contract Terms, Obligations, and Management
   i. Contract Negotiations
C. Institutional Review Board (IRB) Review Procedures
D. Participant Records
   i. Case Report Form Development and Monitoring
   ii. Documentation
E. Monitoring by Sponsor/Contract Research Organization
F. Drug Accountability, Storage, Dispensing and Return
G. Handling of Amendments and Revisions
H. Electronic Correspondence Standard Operating Procedures
I. Adverse Event Safety Reports and Assuring Patient Safety
J. Study Termination (Close Out) Visit and Requirements

A. Study-Specific Protocols, Procedures, and Requirements

- Screening Practices. This resource from Ohio State University Center for Clinical and Translational Science provides an overview of the steps involved in screening study participants.
- Study Protocol. Alliance for Clinical Trials in Oncology. This resource outlines clinical trial definitions and conduct for Alliance clinical trials.

B. Contract Terms, Obligations, and Management

- Model Agreements and Guidelines International. Model Clinical Trial Agreement (Search "clinical trial agreement")
- Baer AR, Hohneker JA, Stewart TL, et al. Negotiating for Success: Navigating the Contracting Process for an Exemplary Research Program. J Oncol Pract. 2010; 6(2):107-110. This article from the ASCO Exemplary Attributes series shares expert advice and negotiation tips to assist sites with contract negotiations.
- Proposed Standardized/Harmonized Clauses for Clinical Trial Agreements. This resource, jointly developed by the National Cancer Institute and the CEO Roundtable on Cancer, provides sample contract clauses to facilitate research contract negotiations.
- Contract Negotiations for Clinical Trials At-a-Glance summary. This ASCO Research Community Forum resource provides key tips, considerations, and strategies to facilitate contract negotiations at research sites.

i. 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. J Oncol Pract. 2016; 12(6):e626-e632.
- 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).

C. Institutional Review Board (IRB) Review Procedures

(e.g., processes, submissions, reviews, approvals, renewals, compliance documentation, etc.)

- U.S. Food and Drug Administration. Institutional Review Board Frequently Asked Questions. 1998. The following is a compilation of answers to questions asked of FDA regarding the protection of human subjects of research.
- U.S. Food and Drug Administration. Institutional Review Board Written Procedures: Guidance for Institutions and IRBs. 2018.
- The Central Institutional Review Board (CIRB) is sponsored by the NCI in conjunction with the Department of Health and Human Services Office for Human Research Protections (OHRP). CIRB conducts full board review of Cooperative Group trials, reducing workload for the local IRB and speeding up trial implementation time.

- Working With Your Institutional Review Board. This article from the ASCO exemplary attributes series
- Office of Human Research Protections. Membership Requirements for Institutional Review. (Video) This video from the U.S. Department of Health and Human Services (HHS) reviews Institutional Review Board requirements and related HHS regulations and policies.

D. Participant Records

(e.g., source documents, requirements/processes for accessing, maintaining, etc.)

- Nova Southeastern University Standard Operating Procedure for Good Clinical Practice.

i. Case Report Form Development and Monitoring

- The National Center for Complementary and Integrative Health (NCCIH) Clinical Research Toolbox includes resources on start-up, case report forms, protocol documents, regulatory, quality management, and other topics.
- National Cancer Institute Division of Cancer Prevention. Manual for the Use and Completion of the NCI, Division of Cancer Prevention Template Case Report Forms (Direct file download) and sample Case Report Form (Direct file download).
- Data management: CRFS and Source Documentation. This resource from Ohio State University Center for Clinical and Translational Science provides an overview of and considerations around data management, including source documentation, case report forms, and data collection tools.

ii. Documentation

(Regulatory documentation, source documentation, Institutional Review Board (IRB) documentation, etc.)

- U.S. Department of Health and Human Services and the U.S. Food and Drug Administration. Information Sheet Guidance for Sponsors, Clinical Investigators, and IRBs (Form FDA 1572). 2010.
- Regulatory Documentation. This resource from the Ohio State University Center for Clinical and Translational Science provides an overview of necessary regulatory documentation for clinical trials.
- St Germain D, Denicoff AM, Dimond EP. Use of the National Cancer Institute Community Cancer Centers Program Screening and Accrual Log to Address Cancer Clinical Trial Accrual. J Oncol Pract. 2014; 10(2):e73-e80.
- Chittester B. How to Properly Make a Correction to a Research Record. IMARC Research, Inc. 2014.
- Heering C. What Errors do we Miss in Clinical Trials? Pharmaceutical Executive. 2016; 38(3).

E. Monitoring by Sponsor/Contract Research Organization

- Site Monitor Visits. This resource from the Ohio State University Center for Clinical and Translational Science provides an overview of what to expect during the various types of site monitor visits.
- Preparing for a Monitoring Visit. (Direct file download) This presentation from the National Cancer Institute Center for Cancer Research provides an overview of the monitoring process and describes strategies for effective preparation for monitoring visits.
- Velesamy M. Advice for Site Monitor Visits Every Clinical Research Coordinator Should Know. GCPcafe.com. 2017.
- Refer to **B. Study Activation** for more information on pre-study site visits.

F. Drug Accountability, Storage, Dispensing and Return

- Drug Supply Management and Accountability. This resource from the Ohio State University Center for Clinical and Translational Science provides information on effective drug supply management, including sample tracking logs.
- National Institutes of Health Investigational Drug Accountability Training Videos provide step-by-step guidance on various aspects of drug accountability.

G. Handling of Amendments and Revisions

- General Information and Instructions for Protocol and Information Amendments. This resource, hosted by Duke University, answers some common questions about protocol amendments.
- U.S. Food and Drug Administration (FDA) Investigational New Drug Application: Protocol Amendments. Review the FDA's definitions of protocol amendment types. 2015.
- U.S. Food and Drug Administration 21 CFR 312.30 - Protocol Amendments.

H. Electronic Correspondence Standard Operating Procedures

- University of New Mexico. Standard Operating Procedure for Use of Web-based Software for Human Research Review Committee (HRRC) and Human Research Protections Office (HRPO) Review/Operations.

I. Adverse Event Safety Reports and Assuring Patient Safety

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.

- Common Terminology Criteria for Adverse Events (CTCAE). This resource, from National Cancer Institute Cancer Therapy Evaluation Program, provides CTCAE guidance for versions 3-5 and Common Toxicity Criteria.
- U.S. Department of Health & Human Services. Guidance on Reviewing and Reporting Unanticipated Problems Involving Risks to Subjects or Others and Adverse Events.
- National Cancer Institute Guidelines for Investigators: Adverse Event Reporting Requirements for DCTD (CTEP and CIP) and DCP INDs and IDEs
- Office of Human Research Protections. Reviewing and Reporting Unanticipated Problems Involving Risks to Subjects or Others and Adverse Events: OHRP Guidance. 2007
- Levit LA, Perez RP, Smith DC, et al. Streamlining Adverse Events Reporting in Oncology: An American Society of Clinical Oncology Research Statement. J Clin Oncol. 2018. 36(6):617-623. This article presents recommendations for streamlining adverse events reporting to make the process as meaningful and informative as possible based on a 2017 ASCO workshop.
- 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 and Drug Administration. 2010.
- Ensuring Patient Safety and Scientific Credibility in Clinical Trials. J Oncol Pract. 2008; 4(2):83-84.
- Human Subjects Research Regulations. This resource from Ohio State University Center for Clinical and Translational Science provides an overview of federal regulations related to protecting study participants.

J. Study Termination (Close Out) Visit and Requirements

- University of New Mexico. Standard Operating Procedure for Suspension or Termination of Human Research Review Committee approval.
- University of New Mexico. Standard Operating Procedure for Project Closure.

V. Management of Trial Participants

These resources address the varied aspects of patient involvement in the clinical trial process. The resources cover topics including eligibility and accrual, consent process, adverse event/serious adverse event reporting, and specimen protocols. This list is not exhaustive and will be updated periodically.

This section includes the following topics:

A. Engaging Patients in your Research Program
   i. Representation of Underserved Populations
   ii. Geographic Barriers
   iii. Barriers to Enrolling Patients onto Clinical Trials
   iv. Broadening Eligibility Criteria
   v. Special Patient Populations
   vi. Financial Barriers for Patients
B. Patient Recruitment and Eligibility
C. Informed Consent Development, Implementation, and Documentation
D. Patient Management While on Study and Long-term Follow-up
E. Specimen Collection, Handling, Processing, Transporting and Destruction
F. Protocol Deviation Reporting and Prevention
G. Emergency Use of an Investigational Drug or Biologic Agent

A. Engaging Patients in your Research Program

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

- Advocacy Program Research Awareness Event Tool Kit for Community Cancer Centers. (Direct file download) This Research Advocacy Network toolkit offers information on how to plan a successful symposium to identify and support research advocates.
- Five Steps to Enhance Patient Participation in Cancer Clinical Trials Guide and Workbook. (Direct file download) This resource from the Education Network to Advance Cancer Clinical Trials offers resources including checklists, common questions, and sample plans to facilitate patient participation in clinical trials.
- Perlmutter J, Bell SK, and Darien G. Cancer Research Advocacy: Past, Present, and Future. Cancer Res. 2013 ;73(15):4611-5. This article discusses the role of cancer advocates in research and presents a framework for successful research advocacy.
- Research Advocacy Network. Advocacy Program Research Awareness Event Tool Kit for Community Cancer Centers.
- Perlmutter J, Roach N, Smith ML. Involving Advocates in Cancer Research. Semin Oncol. 2015; 42(5):681-685.
- 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. J Cancer Educ. 2015; 30:197-203.

- Perlmutter J, Bell SK, Darien G. Cancer Research Advocacy: Past, Present, and Future. Cancer Res. 2013; 73:4611-4615.
- Health Literacy in Clinical Trials. The Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard. www.mrctcenter.org/health-literacy.
- Refer to **Chapter X. Research Organizations and Initiatives** for information on other organizations that offer resources for researchers.

i. 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. J Oncol Pract. 2018; 14(1):e1-e10.

ii. 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 Netw Open. 2018; 1(4):e181235.
- Virani S, Burke L, Remick SC, et al. Barriers to Recruitment of Rural Patients in Cancer Clinical Trials. J Oncol Pract. 2011; 7(3):172-177.
- Galsky MD, Stensland KD, McBride RB, et al. Geographic Accessibility to Clinical Trials for Advanced Cancer in the United States. JAMA Intern Med. 2015; 175(2):293-295.

iii. 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 hasn't 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. 2017; 37:139-143.
- 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. 2016; 35:185-98.
- 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. J Clin Oncol. 2018; 36(16):1603-1610.
- Somkin CP, Ackerson L, Husson G, et al. Effect of Medical Oncologists' Attitudes on Accrual to Clinical Trials in a Community Setting. J Oncol Pract. 2013; 9(6):e275-e283.

- American Cancer Society Cancer Action Network. Barriers to patient enrollment in therapeutic clinical trials for cancer: A landscape report. 2018.
- Staples JN, Lester J, Andrew L, et al. Language as a Barrier to Cancer Clinical Trial Accrual: Assessing Consenting Team Knowledge and Practices for Cancer Clinical trial Consent Among Low English Fluency Patients. Appl Cancer Res. 2018; 38(14).
- Nipp RD, Hong K, Paskett ED. Overcoming Barriers to Clinical Trial Enrollment. Am Soc Clin Oncol Ed Book. 2019; 39:105-114.

iv. 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 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. J Clin Oncol. 2017; 35(33):3737-3744.
- Beaver JA, Ison G, Pazdur R. Reevaluating Eligibility Criteria – Balancing Patient Protection and Participation in Oncology Trials. N Engl J Med. 2017. 376(16):1504-1505.

v. Special Patient Populations

Special patient populations, including older adults, children, and people with disabilities, require attention to ensure inclusion in clinical trials. Review the below resources to learn about considerations for inclusion of special populations in clinical trials.

- Sedrak MS, Mohile SG, Sun V, et al. Barriers to Clinical Trial Enrollment of Older Adults with Cancer: A Qualitative Study of the Perceptions of Community and Academic Oncologists. J Geriatr Oncol. 2020; 11(2):327-334.
- U.S. Food and Drug Administration. Inclusion of Older Adults in Cancer Clinical Trial Draft Guidance for Industry. 2020.
- U.S. Food and Drug Administration. Cancer Clinical Trial Eligibility Criteria: Minimum Age Considerations for Inclusion of Pediatric Patients. Guidance for Industry and IRBs. 2020.
- U.S. Food and Drug Administration. Public Workshop: Evaluating Inclusion and Exclusion Criteria in Clinical Trials Workshop Report. 2018.
- U.S. Food and Drug Administration. Enhancing the Diversity of Clinical Trial Populations — Eligibility Criteria, Enrollment Practices, and Trial Designs. Draft Guidance for Industry. 2019.

vi. 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 Oncol. 2016; 2(1):137-139.
- Winkfield KM, Phillips JK, Joffe S, et al. Addressing Financial Barriers to Patient Participation in Clinical Trials: ASCO Policy Statement. J Clin Oncol. 2018; 36(33):3331-3339.

B. Patient Recruitment and Eligibility

The resources below will aid in developing strategies to improve and streamline recruitment and enrollment in your clinical trial program. Consider addressing barriers to patient participation, including language barriers, to increase number and diversity of patients included on trial.

- Clinical Trials. Cancer.net offers information and resources designed for patients about clinical trials. Refer to **IX. Patient Resources** for more resources from Cancer.net about clinical trials.
- Huang GD, Bull J, Johnston McKee K, et al. Clinical Trials Recruitment Planning: A Proposed Framework From the Clinical Trials Transformation Initiative. Contemp Clin Trials. 2018; 66:74-79.
- Rubin EH, Scroggins MJ, Goldberg KB, et al. Strategies to Maximize Patient Participation in Clinical Trials. Am Soc Clin Oncol Ed Book. 2017; 37:216-221.
- Society for Clinical Research Sites (SCRS) White Papers. Recruiting Diverse Patient Populations in Clinical Studies: Factors that Drive Site Success. 2018.
- Forte Research. Patient Recruitment in Clinical Trials: Steps to Develop a Successful Enrollment Strategy. 2017.
- Increasing Clinical Trial Accrual: Collaboration and Physician-to-Physician Contact. J Oncol Pract. 2007; 3(3):152-153.
- Powell BL, Olson D, Morrell RM, et al. Increasing Clinical Trials Accrual at a Comprehensive Cancer Center. Blood. 2014; 124(21):1266.

C. Informed Consent Development, Implementation, and Documentation

- National Cancer Institute. Describes Recommendations for the Development of Informed Consent Documents for Cancer Clinical Trials.
- The U.S. Department of Health and Human Services Informed Consent Checklist covers the basic elements of the informed consent process and documentation.
- Baer AR, Good M, Schapira L. A New Look at Informed Consent for Cancer Clinical Trials. J Oncol Pract. 2011; 7(4):267-270. This article from the ASCO Exemplary Attributes series details the elements of an effective informed consent document and an effective informed consent process.
- Informed Consent in Research. This resource from the Ohio State University Center for Clinical and Translational Science provides an overview of the informed consent process and provides resources to facilitate the process.
- Office of Human Research Protections. General informed consent requirements (Video). This video from the U.S. Department of Health and Human Services uses case studies to explore

common informed consent issues including capacity to consent, using a legally authorized representative, and meeting the regulatory requirements for the process of informed consent.
- Patient Safety in Clinical Trials. This Cancer.Net resource for patients addresses common questions related to safety in clinical trials.

D. Patient Management While on Study and Long-term Follow-up

(i.e., during treatment and protocol-specified shorter-term and long-term follow-up)

- A Manual for Participants in Clinical Trials of Investigational Agents Sponsored by DCTC, NCI. This manual from the Division of Cancer Treatment and Diagnosis (DCTD), National Cancer Institute (NCI) includes policies and procedures related to various elements of the development of new investigational agents.
- Oncology Research Professional Manual. This resource from SWOG provides strategies and helpful information, including templates, to facilitate long-term follow-up for study participants.
- Subject Management and Site Activities. This resource from the Ohio State University Center for Clinical and Translational Science provides information about key areas in managing study participants.

E. Specimen Collection, Handling, Processing, Transporting and Destruction

- U.S. Food and Drug Administration. Code of Federal Regulations.
- Baer AR, Smith M, Collyar D et al. Issues Surrounding Biospecimen Collection and Use in Clinical Trials. J Oncol Pract. 2010; 6(10):206-209. This article from the ASCO Exemplary Attributes series discusses ethical and regulatory considerations surrounding biospecimen research.
- Office for Human Research Protections. Issues to Consider in the Research Use of Stored Data or Tissues. This resource from the U.S. Department of Health and Human Services provides guidance around operating human cell repositories.
- Baer AR, Collyar D, Smith M et al. Cancer Genomics: Conducting Exemplary Trials with Biospecimen and Biomarker Components. J Oncol Pract. 2010; 6(3):164-167. Part of the ASCO Exemplary Attributes series, this article addresses procedural requirements for clinical trials with biospecimen and biomarker components.
- Biospecimen SOPs from NRG Oncology Manual of Operations and Standard Operating Procedures for the San Francisco Biospecimen Bank. (PDF Download) This resource details the NRG Oncology Biospecimen Bank's operations and includes helpful templates and sample documents.

F. Protocol Deviation Reporting and Prevention

(e.g., U.S. federal regulations, avoiding deviations)

- U.S. Food and Drug Administration. 21 CFR Parts 312 and 316 – Expanded Access to Investigational Drugs for Treatment Use (Direct file download).

- University of Cincinnati. Avoiding Protocol Deviations in Clinical Research. This information provides an overview of protocol deviations, case studies, and steps for documentation and reporting.
- Noncompliance and Protocol Deviations (Direct file download). This presentation from Yale University covers noncompliance, reporting procedures, corrective, and preventive action (CAPA) plans, and IRB action.
- National Cancer Institute Division of Cancer Prevention. Standard Operating Procedure on Recording and Reporting Protocol Deviations

G. Emergency Use of an Investigational Drug or Biologic Agent

(e.g., U.S. federal policies, procedures)

- U.S. Food and Drug Administration. Information Sheet: Treatment Use of Investigational Drugs.
- U.S. Food and Drug Administration. Investigational New Drug (IND) Application.
- Mayo Clinic Human Research Protection Program Procedure for Emergency Single-Case Use of an Investigational Device, Drug or Biologic Product.

VI. Data Management

The resources listed below provide information on how to collect and manage research data. Resources on data protection are also provided. This list is not exhaustive and will be updated periodically.

This section includes the following topics:

A. Disaster Recovery Plan

(i.e., disaster recovery and business continuity plan)

- Business continuity plan. This FEMA resource diagrams a business continuity plan and offers resources to help sites plan for disaster.
- Disaster preparedness and recovery plan. This resource from the U.S. Small Business Administration provides an overview of disaster preparedness.
- Guide to getting started with disaster recovery. This guide from the Disaster Recovery Guide provides information, guidance, tips, and resources to support sites in establishing business continuity plans.
- Disaster Recovery Information Exchange. This non-profit association of professionals is dedicated to the exchange of information on all aspects of business continuity management, from emergency response to the resumption of business as normal.

B. Data Protection

(e.g., protocols, passwords)

- U.S. Department of Health and Human Services Office for Human Research Protections. Data Management Practices.
- U.S. Food and Drug Administration. Good Clinical Practice and Clinical Trial Guidance Documents for information on the agency's perspective on good clinical practice and the conduct of clinical trials.

C. Data Management and Storage

(e.g., short-term and long-term data management, storage, and archiving)

- Corn M. Archiving the Phenome: Clinical Records Deserve Long-term Preservation. J Am Med Inform Assoc. 2009; 16(1):1-6. This article discusses the importance of long-term record storage and address common questions.
- National Cancer Institute. Best Practice for Biospecimen Resources. These voluntary guidelines provide an outline of how to incorporate Best Practices into a site's internal procedures. The guidelines are divided into two broad areas including "Technical and Operational Best Practices" and "Ethical, Legal, and Policy Best Practices."

- National Cancer Institute Office of Biorepositories and Biospecimen Research. Technical and Operations Best Practice: Biospecimen Collection, Processing, Storage, Retrieval, and Dissemination.

D. Managing Equipment and Facilities

(i.e., handling and managing equipment, instruments, and laboratory facilities)

- National Center for Biotechnology Information Prudent Practices in the Laboratory: Handling and Management of Chemical Hazards. This online book discusses environment, health, and safety management systems, administrative and organizational concerns around the laboratory environment, practical concerns, and relevant federal regulations around research laboratory practices.
- NIH Department of Acquired Immunodeficiency Syndrome (AIDS). Requirements for Pharmacy Facilities at Division of AIDS Supported Clinical Research Sites. This site provides policies and standard procedures related to requirements for DAIDS-supported pharmacies and the use of study products associated with DAIDS-supported and/or -sponsored clinical trials.
- World Health Organization. Good Practices for Pharmaceutical Quality Control Laboratories. This resource advises on the quality management system within which the analysis of active pharmaceutical ingredients (APIs), excipients and pharmaceutical products should be performed to demonstrate that reliable results are obtained.

VII. Quality Assurance

The resources listed below cover establishment and assessment of research site quality. Resources provide information on how to create internal quality assessment programs, FDA auditing, and patient safety, among other topics. These resources also feature the ASCO Research Program Quality Assessment Tool.

This section includes the following topics:

A. Data Integrity
B. Internal Quality Assurance Program and Protocol Compliance
C. Quality Improvement
D. Preparing for an Audit

A. Data Integrity

(i.e., accuracy, completeness, legibility, timeliness, etc.)

- U.S. Food and Drug Administration. Providing Post marketing Periodic Safety Reports in the ICH E2C(R2) Format (Periodic Benefit-Risk Evaluation Report) Guidance for Industry. This guidance describes the conditions under which applicants can use the ICH E2C(R2) Periodic Benefit-Risk Evaluation Report (PBER). (Nov 2016)
- International Code of Harmonisation (ICH) Clinical Safety Data Management: Definitions And Standards For Expedited Reporting E2A. This document provides standard definitions and terminology for clinical safety reporting.
- National Cancer Institute. Data Safety and Monitoring Plan. This resource provides links to important information on National Institutes of Health polices and guidance around data and safety monitoring.
- Ohmann C, Kuchinke W, Canham S. et al. Standard Requirements for GCP-Compliant Data Management in Multinational Clinical Trials. Trials 12**,** 85 (2011). https://doi.org/10.1186/1745-6215-12-85.
- Bargaje C. Good Documentation Practice in Clinical Research. Perspect Clin Res. 2011; 2(2):59-63. This article highlights the key principles of good documentation practice and offers suggestions for improvement.

B. Internal Quality Assurance Program and Protocol Compliance

(Internal quality assurance protocols, procedures, and compliance; minimum quality standards; periodic operational checks and audits of protocol data collection, handling, and processing; periodic internal quality control checks and audits of entire program)

- ASCO Research Program Quality Assessment Tool and Manual, which includes a checklist and templates, is available for free online. Email research@asco.org.
- Quality Assurance and Educational Standards for Clinical Trial Sites. J Oncol Pract. 2008; 4(6):280-282. This article, which builds on the ASCO Exemplary Attributes series, discusses how quality assurance and formal maintenance of high educational standards contribute to optimal site function.

- FDA Audit Readiness Toolkit. ASCO Research Community Forum. 2019. Email research@asco.org.

C. Quality Improvement

Resources in this section provide information and strategies for identifying and implementing strategies to improve the quality of your site processes.

- Daudelin DH, Selker HP, and Leslie LK. Applying Process Improvement Methods to Clinical and Translational Research: Conceptual Framework and Case Examples. Clin Transl Sci. 2015; 8(6): 779–786.
- Using Change Concepts for Improvement. This resource from Institute for Healthcare Improvement offers strategies to help with developing site-specific quality improvement tactics.

D. Preparing for an Audit

(Sponsor audits: monitoring, inspections, requirements, policies, and procedures, documentation; FDA audits: requirements, policies and procedures, documentation, corrective action plans)

- How to Prepare for an FDA Inspection. This resource from the Johns Hopkins University Office of Human Subjects Research Institutional Review Board provides a brief overview of basic considerations for FDA inspections.
- FDA Audit Readiness Toolkit. ASCO Research Community Forum. 2019. Email research@asco.org.
- Buchmeier AD. US Food and Drug Administration Clinical Investigator Inspections. Semin Oncol Nurs. 2020; 36(2).
- How to Prepare for an Audit. J Oncol Pract. 2009; 5(1):35-37. This article, which builds on the ASCO Exemplary Attributes series, reviews the audit process including the purpose of audits and how to complete the process.
- National Cancer Institute (NCI). Guidelines for Auditing Clinical Trials for the NCI National Clinical Trials Network (NCTN) Program Including NCI Community Oncology Research Program (NCORP) and NCORP Research Bases.

VIII. Clinical Trial Design and Methodology

These resources describe key terms in precision medicine and clinical trial types and designs. Definitions are provided below.

This section includes the following topics:

A. Precision Medicine Trials and Important Definitions
B. Other Types of Trials and Important Definitions
C. Statistical Considerations for Trial Designs and Methodologies
D. Clinical Trial Terms — Resources

A. Precision Medicine Trials and Important Definitions

Precision medicine is an approach for disease treatment and prevention that considers individual variability in genes, environment, and lifestyle for each person. It allows doctors and researchers to more accurately predict treatment and prevention strategies for a particular disease that will work best in specific groups of people. This approach is in contrast to traditional disease treatment and prevention strategies that are developed for the average person, with less consideration for individual differences. (National Institutes of Health Genetics Home Reference)

- **Basket Trial:** Basket trials test the effect of one drug on a single mutation in a variety of tumor types, at the same time. These studies also have the potential to greatly increase the number of patients who are eligible to receive certain drugs relative to other trials designs. (National Cancer Institute [NCI] Dictionary of Terms)
- **Umbrella Trial:** Umbrella trials have many different treatment arms within one trial. People are assigned to a particular treatment arm of the trial based on their type of cancer and the specific molecular makeup of their cancer. (National Cancer Institute [NCI] Dictionary of Terms)
- **Targeted Therapy:** Targeted therapy is a type of treatment that uses drugs or other substances to identify and attack specific types of cancer cells and limiting harm to normal cells. Some targeted therapies block the action of certain enzymes, proteins, or other molecules involved in the growth and spread of cancer cells. Other types of targeted therapies help the immune system kill cancer cells or deliver toxic substances directly to cancer cells to kill them. This type of therapy may have fewer side effects than other types of cancer treatment. (National Cancer Institute [NCI] Dictionary of Terms)
- **Molecular Profiling:** Molecular profiling is a method of testing genetic characteristics as well as any unique biomarkers of a cancerous tumor. The results are used to identify and create targeted therapies, which are designed to work most effectively for specific cancer tumor profiles. (Leukemia and Lymphoma Society Cancer Molecular Profiling)
- **Genomic Profiling:** Genomic profiling is laboratory method use to learn more about the genetic makeup of a person or cell type and the way those genes interact with each other and the environment. This method may inform why some people get certain diseases while others do not, or why people react in different ways to the same drug. It may also be used to help develop new ways to diagnose, treat, and prevent diseases, such as cancer. (National Cancer Institute [NCI] Dictionary of Terms)

- **Precision Medicine Initiative:** The PMI is a $215 million proposed investment in President Obama's 2016 Budget to accelerate biomedical research and provide clinicians with new tools to select the therapies that will work best in individual patients. The PMI's near-term emphasis is on cancer, and other disease areas will be included over the longer term. (National Cancer Institute [NCI] and the Precision Medicine Initiative)

B. Other Types of Trials and Important Definitions

- **Cancer Care Delivery Research:** Cancer Care Delivery Research (CCDR) examines how social factors, financing systems, organizational structures and processes, health technologies, and healthcare provider and individual behaviors affect cancer outcomes, access to and quality of care, cancer care costs, and the health and well-being of cancer patients and survivors. Ultimately, it aims to reduce the incidence, associated symptoms, and morbidities of cancer and its treatment, and enhance the quality of life of those affected by cancer. (National Cancer Institute Community Oncology Research Program [NCORP] Research Areas)
- **Treatment Trials:** Treatment trials are designed to test new ways to treat cancer. For a treatment to become standard, it must usually go through 3 or 4 clinical trial phases. The early phases make sure the treatment is safe. Later phases show if it works better than the standard treatment. (National Cancer Institute Types of Clinical Trials)
    - **Phases of Clinical Trials:** For a treatment to become standard, it must first go through 3 or 4 clinical trial phases. The early phases make sure the treatment is safe. Later phases show if it works better than the standard treatment. Each phase of a clinical trial is designed to provide different information about the new treatment, such as the dose, safety, and efficacy (how well it works). The phases are described as I, II, and III. (National Cancer Institute Phases of Clinical Trials; Cancer.net Phases of Clinical Trials)
    - **Phase I Clinical Trial:** An experimental drug or treatment, which has proven to be safe for use in animals, is tested in a small group of people (15-30) for the first time. Data are collected on the dose, timing, and safety of the treatment. The purpose is to evaluate its safety and identify side effects. (National Cancer Institute Phases of Clinical Trials; Cancer.net Phases of Clinical Trials)
    - **Phase II Clinical Trial:** An experimental drug or treatment is tested in a larger group (100 or less) to provide more detailed information about the safety of the treatment, in addition to evaluating how well it works for a broader range of people. Phase II trials usually take about two years to complete. (National Cancer Institute Phases of Clinical Trials; Cancer.net Phases of Clinical Trials)
    - **Phase III Clinical Trial:** Before an experimental drug or treatment is approved by the FDA and made available to the public, Phase III trials are conducted on a large group of people (from 100 to several thousand). At least two (and often more than two treatment options, including standard of care) are compared to find out whether the new treatment is better, and possibly has fewer side effects, than the current standard treatment. Phase III clinical trials are usually randomized, meaning that patients receive either the investigational drug or treatment or another drug or treatment in a non-ordered way. (National Cancer Institute Phases of Clinical Trials; Cancer.net Phases of Clinical Trials)

    - **Phase IV Clinical Trial:** After a drug is approved by the FDA and made available to the public, researchers track its safety, seeking more information about a drug or treatment's risks, benefits, and optimal use. Several hundred to several thousand people participate in Phase IV trials. (Cancer.net Phases of Clinical Trials)
- **Health Services Research:** Multidisciplinary research that examines how social factors, financing systems, organizational structures and processes, health technologies, and personal behaviors affect access to health care, the quality and cost of health care, and ultimately our health and well-being. Its research domains are individuals, families, organizations, institutions, communities, and populations. (Agency for Healthcare Research and Quality an Organizational Guide to Building Health Services Research Capacity)
- **Cancer Prevention Studies:** A cancer prevention trial is a study of a large group of people. A prevention trial tries to find better ways to prevent people from getting cancer or lower the chances that people will get it. (U.S. Department of Health and Human Services [HHS] If You Want to Find Ways to Prevent Cancer… Learn About Prevention Clinical Trials)
- **Prognostic Studies:** Studies that aim to understand the course, determinants, or probability of a given outcome in cohort (Cochrane Methods Prognosis About Us)
- **Experimental Studies:** As part of an experimental study, researchers provide an intervention (such as a treatment) to a group of individuals and compare their results to those of another group that does not receive the intervention (known as the control group). The researchers decide who receives the intervention and who does not either randomly (for reasons explained below) or through intentional selection. Experimental studies can investigate treatments, correlative science (testing whether specific genes or proteins affect the development or spread of cancer), new imaging techniques, and quality of life issues. (Cancer.net Understanding Cancer Research Study Design and How to Evaluate Results)
- **Observational Studies:** During an observational study, the researchers observe groups in which the intervention that each person receives is not controlled by the researchers. Observational studies tend to be epidemiologic (relating to how various risk factors cause or affect the development of a disease in a population). (Cancer.net Understanding Cancer Research Study Design and How to Evaluate Results)
- **Comparative Effectiveness Research:** Comparative effectiveness research is the conduct and synthesis of systematic research comparing different interventions and strategies to prevent, diagnose, treat and monitor health conditions. The purpose of this research is to inform patients, providers, and decision-makers about which interventions are most effective for which patients under specific circumstances. (National Library of Medicine Resources for Informing Comparative Effectiveness Research)

C. Statistical Considerations for Trial Designs and Methodologies

- Statistical Considerations in Oncology Trials | ASCO eLearning Fundamentals of Clinical Trials.
- Ellis LM, Bernstein DS, Voest EE. American Society of Clinical Oncology Perspective: Raising the Bar for Clinical Trials by Defining Clinically Meaningful Outcomes. J Clin Oncol. 2014; 32(12):1277-1280.
- Clinical Trial Eligibility Criteria. This asco.org web page provides an overview of ASCO's initiative on broadening eligibility criteria.

D. Clinical Trial Terms — Resources

- Genetics Home Reference. This website from the U.S. National Library of Medicine provides consumer-friendly information about human genetics, including the effects of genetic variation on human health.
- NIH Clinical Research Trials and You.
- ASCO Cancer.Net Information for Patients.
- National Cancer Institute Dictionary of Genetics Terms. This resource provides technical definitions for many terms related to genetics.
- National Cancer Institute Dictionary of Cancer Terms. This resource provides definitions for many terms related to cancer and medicine.
- ASCO eLearning: Fundamentals of Clinical Trials.

IX. Patient Resources

Cancer.Net provides timely, comprehensive, oncologist-approved information from ASCO that brings expertise and resources to people living with cancer and those who care for and about them, to help patients and families make informed health care decisions. These resources from Cancer.Net provide information, written with patients in mind, on varied topics related to cancer, healthcare and the medical field, and clinical research.

This section includes the following topics:

A. Information for your Cancer Journey

The following resources provide helpful information for those beginning their cancer journey.

- Cancer Basics
- How is Cancer Treated
- Questions to Ask Your Health Care Team
- Learning About your Specific Cancer Type
- Financial Considerations

i. General Information

The following resources offer additional information to help learn about cancer.

- Medical News: 8 Ways to Separate Fact from Fiction.
- Evaluating Cancer Information on the Internet.
- Journals and Magazines. This listing covers leading oncology and general-medicine scientific journals and consumer magazines, which may be helpful in finding additional information, services, and support.

B. Introduction to Cancer Research

The following resources provide an overview of cancer research, including information on participating in clinical trials.

- Introduction to Cancer Research.
- Drug Approval and Labeling.
- Clinical Trials. ASCO's patient website, Cancer.Net, offers patient education materials regarding clinical trials. The website also includes patients' stories about their participation in clinical trials and a podcast. All these resources are free to access.

- Taking Part in Cancer Treatment Research Studies. This resource provides information for people with cancer who are thinking about participating in a clinical trial.
- Questions to Ask About Clinical Trials.
- Clinicaltrials.gov is a registry and results database of publicly and privately supported clinical studies of human participants conducted around the world.
- Patient Safety and Informed Consent.
- Health Insurance Coverage of Clinical Trials.

C. Research and Advocacy

- Research and Advocacy.
- PRE-ACT (Preparatory Education about Clinical Trials).
- What is the Patient's Role in Cancer Research?
- How Patient Advocates Help Cancer Research: An expert Q&A.
- Understanding the Publication and Format of Cancer Research Studies.
- Understanding Cancer Research Study Design and How to Evaluate Results.
- Drug Discovery and Development.

X. Research Organizations and Initiatives

The resources below list professional and research organizations that provide information, resources, and opportunities for researchers.

This section includes the following topics:

A. Research Professional Organizations
B. Other Resources

A. Research Professional Organizations

- 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.
- 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.
- Society for Clinical Research Associates (SoCRA). A non-profit organization dedicated to educating and developing clinical research professionals.

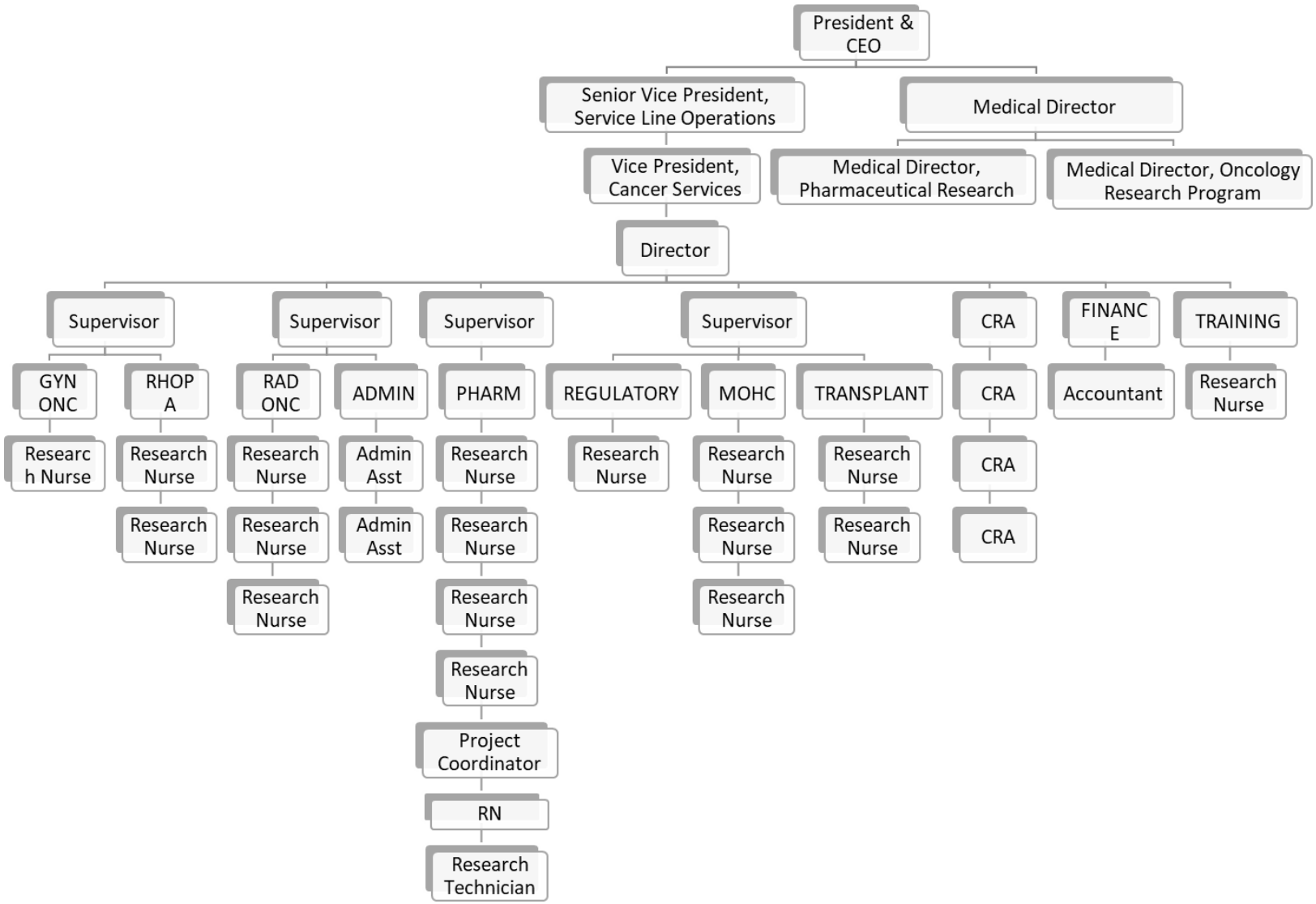
B. Other Resources

- Clinical Trial Transformation Initiative. This initiative 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.
- Public Responsibility in Medicine and Research (PRIM&R). A professional organization that offers research and ethics focused education, membership services, professional certification, public policy initiatives, and community building.
- Patient-Centered Outcomes Research Institution (PCORI). This organization works to improve the quality and relevance of evidence available to help patients, caregivers, clinicians, employers, insures, and policy makers make informed health decisions.
- Model Agreements and Guidelines International (MAGI).
- Grant and Award Opportunities through ASCO. Conquer Cancer, the ASCO foundation, supports numerous grant and award opportunities for academic researchers and community-based practices, some which are based on the Exemplary Attributes of Clinical Trial Sites.

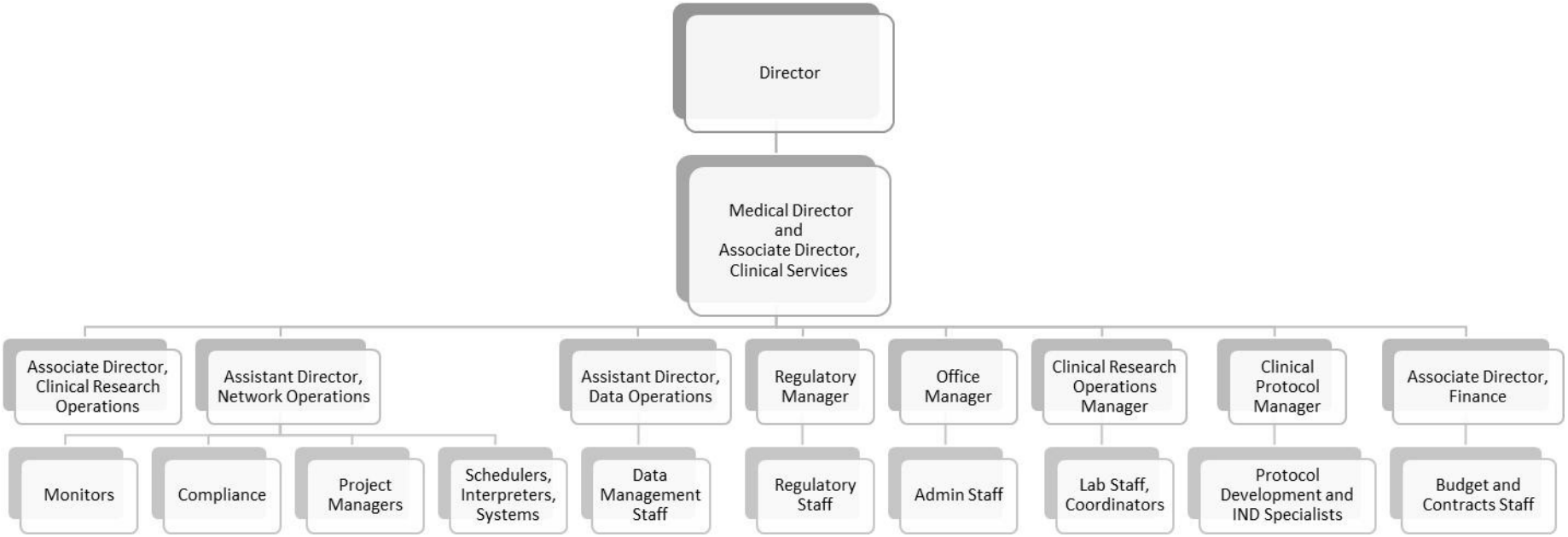
APPENDICES

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 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 can perform 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 before 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 COORDINATOR TRAINING AND ORIENTATION TOOLS

Training	Item	Completion Date	Employee/ Supervisor Initials
Basic Training	ϒ Pre-Orientation Checklist Initiated ϒ Research Department Checklist ϒ 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 ϒ Training in institutional standard operating procedures (SOP) ϒ Viewing of institutional abbreviations and acronyms ϒ Password tracking ϒ If applicable, training in Structure of Cancer Clinical Trial organizations, Cooperative groups & Pharmaceutical sponsors		
CCHS Office of Sponsored Programs (OSP)	ϒ Compete conflict of interest (COI) online form (renew annually) ϒ Effort reporting		
Education Center	ϒ International Air Transport Association (IATA) (bio specimen shipping) online training. ϒ Provide IATA certificate to Office of Clinical Research ϒ Other assigned online training as instructed		
INSTITUTIONAL Training Manual	ϒ See INSTITUTIONAL training manual		
If applicable: Oncology Fundamentals	ϒ Staging: AJCC Staging Manual; (Surveillance, Epidemiology, and End Results) SEER online module https://training.seer.cancer.gov/staging/ and www.cancer.org ϒ Treatment modalities (Oncology Nursing Society (ONS) Core Curriculum Text)		

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

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

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

On-call Requirement	ϒ 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***	ϒ Prescreens patient and communicates information to treating investigator ϒ Maintains screening logs ϒ Adopts an organization system for daily workflow ϒ Prioritizes activities appropriately ϒ Delegates as needed		
	ϒ Coordinates screening and documents appropriately		
	ϒ Obtains Informed Consent and documents appropriately		
	ϒ Creates an Eligibility worksheet		
	ϒ Determines eligibility with 2nd RN review and obtains treating investigator verification and documents appropriately		
	ϒ Enrolls/Registers/Randomizes patient and documents appropriately		
	ϒ Documents in DDOTS/Credit system		
	ϒ Provides Patient Education regarding: o clinical trial participation o ongoing nature of informed consent o schedule and treatment o medication administration and patient documentation o safe handling of oral chemotherapy o key contact information		

	○ documents appropriately ○ Provides IRB approved study updates		
	ϒ 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.		
	ϒ Reports AEs to PI, sponsor and other research team members ϒ Completes SAE submission within required time period.		
	ϒ Responds and completes query response in a timely manner		
	ϒ Completes Documentation within expected timeframes ○ Eligibility ○ Consent ○ Treatment ○ SAE ○ Deviation		
	ϒ Obtains study re-consent when necessary		

	ϒ Completes consent-withdrawal procedure, if necessary		
	ϒ Clinical Staff Education o Provides research topic education to ambulatory infusion staff and/or hospital staff		
Disease Team Communication and Participation	ϒ Actively participates in Disease Team Meetings ϒ 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. ϒ Communicates with Research Pharmacy, treating providers, clinical nursing, and others to ensure an excellent patient experience. ϒ Coordinates data collections and enters data into sponsor data base for analysis. ϒ Assists with the preparation of documents for audit and review by sponsors, regulatory agencies, and internal and external review boards.		
Nursing Team Participation	ϒ Demonstrates willingness to assist colleagues, including other Research RNs, with workload, education, and training.		

Employee Signature
Date

Preceptor/Mentor Signature
Date

Supervisor Signature
Date

CRC Name: **Preceptor Name:**

Hire Date: **Supervisor Name:**

1. Submit a new hire checklist to the practice Site Services Manager for approval.
2. Submit requiredpaperwork to USOR Regulatory Affairs as instructed.
3. The CRC must complete a libraryof learning modules titled the *CRCCore Curriculum*before patient registration privileges will be granted. The modules are located in the Learning Center and are automatically assigned upon hire.
4. The CRC must complete hazardous goods training (HAZMAT or IATA Training is acceptable) within 90 days of employment or change in job function. *HAZMAT Training*is automatically assignedin the Learning Center upon hire.
5. The process for completing this form:
    a. The CRC will sign and date the form when completed throughself-evaluation.
    b. The CRC's direct supervisor or SRL will sign and date the form to confirm CRC training.
6. Appendices A through D areenhancements to the CRC Orientation Checklist and may utilized according to the needs of the Practice.

Topic	CRC Initials/ Date	Preceptor Initials/ Date
Research Document Collection		
Submission of Regulatory Documents as requested by [institution] Regulatory Affairs		
Complete GCP Training and SOP Review		
Research Training Program-Contact Network Operations for Assignment		
Complete the *CRC Core Curriculum* locatedon the Learning Center		
Computer Skills		
Map to Practice drives, Outlook, shared calendars, and personalfolders		
Review Practice EMR (if applicable); submit skills assessment checklist if utilizing iKM		
Review options locatedon My Oncology Workspace (applicable to Networkpractices only)		
Obtain CTMS log-in credentials and successfullynavigate to the system		
Comprehendthe Following CTMS Topics		
Document Consents and Subject Database Entry		
Update Records, Running a List, Links, & Advanced Search		
Patient Calendars, Patient Lists, & Patient Re-consents List		
Queries, Critical Document Checklist, & Payout Report		
Accrual Summary Report, Deviation Summary, & PharmacyeDRAF		
Site Location & Lab Profile Reports		
CRF Tracking		
CRF Roll-up Summary Report		
eDC Basics		
General Research Forms		
eDraft System		
Document RECIST in the eDC System		
Document Deviations in CTMS		

Topic	CRC Initials/ Date	Preceptor Initials/ Date
Research Overview		
Company's Role in the Oncology Community		
Historical Development		
Program Leadership		
Program Accomplishments		
Services Providedto Practice		
Research Process Overview		
Trial Development from Concept to Completion		
Protocol Components		
Randomization-Rationale and Process		
Attend a Monthly Research Network Operations Education/Operations Teleconference or listen to playback		
Phases of Clinical Trials		
Types of Trials, i.e., Registration, Investigator Initiated		
Study-Specific Training		
Informed Consent Process		
Consenting a Patient (must be completed twice to complete this requirement)		
Consenting a Patient (must be completed twice to complete this requirement)		
Re-consent Process		
Documentingand rationale for "withdrawn" patients		
Protocol Eligibility Confirmation		
Protocol Exceptions& Deviations		
Clinical Trial Information(CTI) sheet		
Fast Facts		
Source Documentation Definition		
Calculations-Demonstrate calculations for the following:		
BSA		
ANC		
AUC		
RECIST 1.0 versus 1.1		
Adverse Event Grading and Documentation		
Query Management-Definition, Identification, and Resolution		
Cancer Staging		
Investigational Products Center (IPC) Overview		
Blinded Trials and the un-Blinded Process		
Pharmacy Tools		
Site drug accountability includingreceipt verification, destructionand return		
Ordering study drug from the IPC (must be completed twice to fulfill this requirement)		
Ordering study drug from the IPC (must be completed twice to fulfill this requirement)		
Indicating drug was received (must be completedtwice to fulfill this requirement)		

Topic	CRC Initials/ Date	Preceptor Initials/ Date
Indicating drug was received (must be completedtwice to fulfill this requirement)		
Returning study drug to the IPC		
Ordering Lab Kits for New and Established Subjects		
Pharmacy Queries		
Temperature Log Maintenance and Temperature Excursion Event Process		
Regulatory Overview		
Critical Document Checklist		
Weekly Regulatory Affairs Memorandum		
Regulatory Forms including FDA Form 1572, DRAP, DOR, FDQ, etc.		
Central IRB		
Obtaining a Translated Consent Form		
Practice On-Site File Maintenance		
Process of Opening a Study		
Physician Oversight and Completion of Monthly Physician Oversight Meeting Logs		
Safety Process Overview		
Serious Adverse Event Reporting & Documentation		
IND Safety Report Maintenance		
Obtain List of SAEs Associated with Your Site's Trials		
Research Finance		
Standard of Care (SOC) versus Non-Standard of Care (NSOC)		
Review Site's Financial Processes Including Insurance Pre-authorization, Encounter forms, etc.		
Review Research Charge Ticket (if applicable) and Charge Capture		
Research Billing Guide (RBG)		
Direct Bill Invoicing & Electronic Invoicing (CRF Tracking)		
Capturing Screen Failure Patients Payments		
Medicare Analysis		
Invoicing/checkstatus		
Review Finance Toolkit		
HAZMAT/IATA-General Awareness Training		
Hazardous goods training is requiredfor any employee that ships, receives, or handles drug, tissue samples, or any other material classified as hazardous. *HAZMAT and IATA Training,* locatedin the Learning Center, will fulfill this requirement.		
HAZMAT/IATA-Job Specific Training Checklist		
1. Knows how to access dry ice for shipment at your site		
2. Knows how to access MSDS binder at your site		
3. Demonstrates ability to pack ambient specimenfor shipment		
4. Demonstrates ability to pack refrigeratedspecimen for shipment		
5. Demonstrates correct label placement prior to shipment		
6. Able to locate the *USOR HAZMAT-IATA Regulation Sheet* locatedon CTMS		
HAZMAT/IATA-Safety Training		

Topic	CRC Initials/ Date	Preceptor Initials/ Date
Understands hazardous goodsemergency response information and procedures, methods to avoid exposure, and methods to avoid accidents.		
Completed OSHA requiredtraining		
HAZMAT/IATA-Security Training (Site Specific)		
Understands the character of security risks		
Understands security risks exists and methods to minimize the risks		
Understands the processes to reduce security risks		
Understands the steps to take should a security risk occur		

Clinical Research Coordinator (CRC) Orientation Completion Information

CRC Signature & Date: **Preceptor Signature & Date:**

Completion Date: **Supervisor Signature & Date:**

Appendix A-Practice Infrastructure Training

Appendix A was designedto provide guidance to the Preceptor/Supervisor who will assist the CRC in becoming acclimated to the Practice and its processes.

Topic	CRC Initials/ Date	Preceptor Initials/ Date
Practice Management/Administration		
Documentationof professional license, certifications, CPR, etc. (typically collected prior to hire)		
Time Reporting; Process for Scheduling Vacations Time, Flex-time, Breaks, etc.		
Procedure for Sick Days		
Obtain Employee Badge/Name Tag and Employee ID Number (Network Practices Only)		
Hepatitis & TB testing		
Training File		
Review Job Description		
Tour Facility/Employee Introductions		
Obtain Practice Telephone List and Physician Coverage Schedule		
Supervisor/Preceptor to Arrange On-Site Orientation with Different Departments		

Appendix B- Orientation to Practice Medical Records

Appendix B was created to document the review of the medical records/chart utilized at the Practice by the new CRC. The CRC should be able to readily identifythe location of all sections listed.

Topic	CRC Initials/ Date	Preceptor Initials/ Date
Nursing Notes		
Physician Progress Notes		
Physician Orders		
Treatment Administration Records		
Chemotherapy Informed Consent Form (if applicable)		
Research Section		
Medication List		
Laboratory Results		
Pathology Results		
Radiology		
Outside Records		
Nursing Notes		

Appendix C- Orientation to the Practice Departments

Appendix C was created as a map for the CRC to guide them through their journey to the different Practice Departments. During Practice Orientation they may use the outline provided to prompt discussions for information they will need in their newrole.

Topic	CRC Initials/ Date	Preceptor Initials/ Date
Executive Director or Practice Administrator		
Expectation of the CRC and the Role of the Research Department Within the Practice		
Nursing (Clinic Nurses and Infusion Room)		
Integrating Research into the Practice		
Hospital Admission Process		
Process for Obtaining Hospital Records		
Symptom Management		
Coordinationof Care		
Working with a Triage Nurse (if applicable)-Triage of Research Patients		
Observe Protocol In-Service to Clinic Nurses		
Observe a Nurse's Meeting		

Topic	CRC Initials/ Date	Preceptor Initials/ Date
Medical Records Department		
Roles, Responsibilities, and Expectations by the Research Staff		
Schedulers		
How Patients are Scheduledfor Appointments & Procedures		
Process for Appointment Cancelation		
Front Office		
Process for Patient Check-in		
Process for Incoming Telephone Calls to the Research Department		
Medical Assistant (MA)		
Roles and Responsibilities		
Pharmacy (Pharmacists and Technicians)		
Admixture		
Drug Storage		
Drug Accountability		
Hood Preparation and Cleaning Logs		
Temperature Logs & Maintenance		
Laboratory		
Lab Reference Manual		
Identification of Research Lab Processing		
Process & Sending of Lab Kits		
Temperature Logs & Maintenance		
Completion of Lab Kit Requisition Form		
Financial Counselor		
Patient Pre-authorizationfor a Clinical Trial		
Third Party Payors		
Insurance Denials		
Billing		
Research Billing Process for the Practice		
Review Research Charge Ticket		
Review Practice Encounter Form		
Discuss the Purpose of Tracking		
Discuss the Purpose of Negotiating Contracts and Whois Responsible for the Task in the Practice		
Review Q1 Modifiers		
Radiation Therapy		
Discuss How Radiation is Scheduled		
Coordinationof Care with NRG Sites (if applicable)		
Radiology		
Review Scheduling Procedures		
Requesting Tumor Assessments/Completion of Measurement Forms		
Patient Education & Instructions		

Appendix D – Protocol Comprehension

Appendix D was created to be an interactive exercise between the CRC and Preceptor. A protocol shouldbe dissected together and each section should be reviewedto ensure a basic knowledge of protocol components.

Topic	CRC Initials/ Date	Preceptor Initials/ Date
Title Page		
Scientific Rationale		
Study Objectives & Purpose		
Trial Design		
Number of Participants		
Eligibility Criteria		
Treatment Schedule & Duration		
Tests & Procedures Required		
Side Effects & Dose Modification		
Concomitant Medication		
Efficacy Assessment		
Patient Provided Subjective Assessments (QOL, Pain Diaries, etc.)		
Safety Assessment		
Trial Endpoints		
Title Page		
Scientific Rationale		

Trial Training

- ❑ Review the protocol; use control F to quickly searchprotocol
  - Lab, scans, tissue
  - Key Word: Schedule of assessments
  - Key Word: Central
  - Radiology, pathology
  - In CTMS
    - Lab manual
    - Forms
    - CTIs
    - Imaging manuals
    - Lab Flowcharts
  - For amendments
    - If Lab related - print info andplace in binder
- ❑ Complete documentationof training (study specific training sheet for previous trials/ new trials via voting buttons)
- ❑ Review /update cheat sheet in study binders
- ❑ Note every trial must have a cheat sheet createdand keep updated

Labs

1. Study Start Up Labs Ordering (SSU):

- ❑ Institution/Research Network
  - Refer to protocol/CTI on how Central labs handled(bulk - direct from vendor or from IPC)
  - If from IPC - go to study and order screeninglab kit (under pharmacysection - Screening lab kit order form); this is to be emailed to IPC
  - Lab Kits are shipped to Pharmacy
- ❑ Indie trials
  - Typically sent in bulk through lab vendor at study start up - refer to lab manual
- ❑ Once received-Inventoryand enter log on Research shareddrive
  - Clinical Needs-Research Assistant Files - Inventory
  - Store labs in hall - label closet (cabinets organizedby disease)
  - Label with (institution/research network) # if applicable and separate by disease

2. Patient Visit Labs Ordering:

- ❑ Institution/Research Network
  - Refer to CTI - if providedfrom IPC - order via RX under patient name - cycle specific. Order at least 2 weeks in advance - by Tuesday for the following week
  - Typically, can order multiple cycles at a time to keep small supply on hand
  - Once received go to CTMS - patient reports - Pharmacye-draf action items and mark kits received by patient/cycle
- ❑ For INDE order bulk supply thrustudy specific vendor
  - Instructions are provided for ordering thru each portal in Inventoryspreadsheet

**** INDE studies take a long time to receive give a lead of 4-10 weeks for supplies

3. Lab Processing

- ❑ Research Nurse will coordinate the Lab drawing also in IKM
  - Green sheet completedby researchnurse and provided to MA
- ❑ At BAM Labs come back/picks up to/by RA for processing
- ❑ Requisition form is completedby R-RN NEEDS TO BE COMPLETE!!!! (no blanks) MUST HAVE TIME DRAWN ON ALL REQUISITIONS
  - At satellite site the R-RN processes the labs
  - RA double checks requisitions at BAM/KWD
- ❑ Log lab into the site labs log to track sent labs - clinical Needs-Site Labs-Lab trackinglog
  - Shipping of backups- refer to study guidance - bulk ship as study directed. DO NOT SHIP PRIMARY SAMPLES IN THE SAME SHIPMENT AS BACKUPS
  - List ALL labs sending in the comments sectionof site labs log
  - Some trials require back-ups to be batchedand placedin -70 freezer (clipboard at freezer)
- ❑ Dry Ice is needed unless shippingis ambient
- ❑ Shipping label
  - Return address label
  - If shipping dry ice ensure box is appropriatelylabeled (dry ice sticker/ box)
  - Do NOT cover dry ice label
  - Must place on box the weight in kgs. Of package
  - Air bills: Typically(institutions) trials will have air bills in kit; Indie will not, RA will have to see which air bill is neededand put it in at kit prep.
  - Need to schedule with specific studyshipping vendor
    - Fed Ex/UPS - 2-hour window
    - Marken – 4 hours
    - World Carrier - 48-24 hour
    - BRE 12022/193 - portal will designate shipping
- ❑ Lab results come via one of the following- should be outlinedin CTI (if [institution/research network] trial) or lab manual
  - Portal
  - Fax
  - Email
- ❑ RA provide results to R-RN for MD sign off and add to shadow chart - MD to list CS vs NCS

Daily Prep:

- ❑ Refer to Research Note of Treatment (RNOT) for visit (from Research Nurse)
- ❑ Reconcile against Clinical calendar to ensure visit is still happening

Lab Kit Prep:

- ❑ Refer to Research Note of Treatment (RNOT) for visit (from Research Nurse)
- ❑ Reconcile against Clinical calendar to ensure visit is still happening
- ❑ Label kits with patient info - name/ DOB
  - Research Nurse labelscryovialswith study subject number and removes patient identifiersfrom tubes with no processing and labels with study subject number
- ❑ Print instructions (lab manual on CTMS if [institution/research network]Trial, sometimes in kit)
- ❑ Air bills: Typically(institution/research network) trials will have air bills in kit; Indie will not, RA will have to see which air bill is needed and put it in at kit prep
- ❑ Send the kit to site
- ❑ Inventory folder for trackingstudy supplies - update as kits are ordered/sent

Pathology/Tissue - access to portal in RA folder:

- ❑ Be aware of timelines for submission of tissue - add to cheat sheet
  - Pre/post randomization/enrollment
  - Archive vs. Fresh
  - On study
    - Neoadjuvant
    - Maybe sent to a network site review/in addition to central review
- ❑ If Indie trial refer to protocol
- ❑ Binder Cheat Sheet - filled out at SIV
- ❑ Refer to schedule of assessments for tissue (archival vs on study biopsies)
- ❑ Lab manual provides instructions for tissue processing
- ❑ New patient registrationform
  - R-RNS fill out
  - This alerts the RA tissue is required at screening
  - RA reaches out to R-RN to initiate consent of tissue release signature by patient
    - R-RN is responsible for obtaining consent form/ having subject sign it
  - R-RN - Form is filed with consent; RA files copyin tissue files in RA office
  - RA faxes the consent and request from to hospital
  - On request form specifythe type of tissue per study specifications being requestedand whenneeded (i.e. which sample we want from/which block) confirm with nurse that it is the right block if need be. (ASAP for pre-enrollment vs. post enrollment.)
  - Prep kit
    - RA completes all labeling of kits - refer to pathologyreport for info
    - DE IDENTIFY patient info!!!!
    - Send de-identifiedpath report with sample
    - NOTE use correct air bill - could be an international shipment (special custom form needed, found in study binder)
    - Copy air bill/requisition for shadow chart and for RA file
    - Add any tissue request to white board with trial, patient initials and timeline needed, status of tissue, and mark RA that is taking tissue
    - May receive results via - check trial/lab manual via portal/email/fax—this should be on cheat sheet

Trial Oversight – SSU – Tracking:

- ❑ Add Tissue specificationson Tumor Tissue spreadsheet (Clinical Needs - RA files - Tumor Tissue - Tumor Tissue spreadsheet) for trial in O drive
  - Designate randomizationrequirement vs routine
  - Track via white board

Post SIV/Trial Opening:

- ❑ CTI/OHC cheat sheet from SIV/monitor-helpful contacts
- ❑ Lab Manual for INDIE
  - USO lab manual on CTMS
- ❑ Order screeningkits
- ❑ In CTMS
  - Pharmacy tab
  - Kit request forms
    - Screening kits email
    - For other cyclesuse CTMS

- ❑ Create Binders
    - Order kits/print lab manuals
    - Shelf is organized by enrolling/active, enrolling not active
    - International form - customs form for tissue - none currently

Routine Tasks

Dry Ice Coordination

- ❑ How to obtain Dry Ice:
    - Dry ice is automatically sent twice a week (Monday - 1 box to BAM and 1 box to KWD; Wednesday- 1 box to BAM and 1 box to KWD)
    - Will need to call Continental Carbonics (513-674-1300) the weekbefore to change schedule dates
    - Call Continental Carbonics 1-2 days in advance to order EXTRA dryice boxes if needed.
    - Let the courier know of any changes/ additional pickups
- ❑ Send the dry ice shippers daily to sites (do not put dry ice in shippers going to KWD)
- ❑ Freezer and door needs to be unlocked in the AM- the courier deliversthe dry ice directly to Freezer (around 8:30 am)

Equipment Management

- ❑ Daily Logs
    - Freezers
- ❑ Tablet/study supplies will have specific instructions
    - Inventory: Study specific e-pro, e-diaryand EKG log
        - Log all items in spreadsheet-notate which office/patient they are with if sent home with patient
        - Monthly inventory reconciliation of tablets
- ❑ Monthly inventory of kits

Queries

- ❑ Look into queries and findresolutions.
- ❑ Queries canbe generated for multiple areas: tissue, lab, scans

Shared Calendars

- ❑ Review daily

Scans

- ❑ Order
    - Refer to RNOT
    - Fax the request form
    - Put fax request form in RNOT binder until readyto send
- ❑ Familiarize self on portals for uploads
- ❑ Works best to downloadthe desktop versions
- ❑ Scan - permissions for portals refer to CTI
- ❑ Review if patient has consented to optionaltissue/logs
- ❑ Utilize RNOT process/binder
- ❑ Utilize White boards

Responsibilities	Mentor Initials/Date	Trainee Initials/Date
Trial Training Process		
Central Lab Process: ***observe and complete 3*** ▪ Order - Screening vs existing patients ▪ Prep ▪ Process ▪ Spin ▪ Shippers-prep ▪ Send ▪ Spreadsheet tracker ▪ Inventory tracking - completed monthly o Expiration date/tracker ▪ Lab results ▪ Dry Ice ▪ Daily Prep for patient visit		
Research Note of Treatment (RNOT) review		
Study Start-up Process/Procedures ▪ Trial binder development and maintenance		
Tissue Request: ***observe and complete 2*** ▪ Timelines/Processes/ Procedures/References ▪ Tracker ▪ Study Start up		
Scans: ***observe and complete 2 in each portal*** ▪ Request and submission process		
Shared Calendar		
Queries		
Trackers - O drive		
Trial Opening Review		
Trial Distribution		
Routine Tasks: ▪ RNOT Review ▪ Equipment Management ▪ Temperature recording ▪ Dry Ice maintenance ▪ Inventory ▪ Queries ▪ Populating and Reviewing Shared Calendar		

Mentor Signature _____ **Trainee Signature** _____

(Practice Letterhead)

Patient Name: _____
Patient Date of Birth: _____
Patient MRN: _____

Visit Details

Patient ID: _____
Protocol Name: _____
Date of Consent: _____

Documentation of Initial Informed Consent

1.	The patient was given the opportunity to read the Informed Consent Form (ICF) or the Clinical Research Coordinator (CRC) read the ICF to the patient explaining the details of the protocol.	❍ Yes ❍ No
2.	The patient was given adequate time to ask questions and questions were either answered by the CRC, patient's MD/Sub-Investigator, or Principal Investigator of the study.	❍ Yes ❍ No
3.	Alternative treatments were discussed by the treating Investigator.	❍ Yes ❍ No ❍ N/A
4.	Participation is voluntary; Patient may withdraw at any time without penalty.	❍ Yes ❍ No
5.	Informed Consent Form is in the patient's primary language.	❍ Yes ❍ No
6.	Patient was given contact information and instructed to call with any questions or concerns regarding the study.	❍ Yes ❍ No
7.	Patient was provided with a copy of the signed Informed Consent Form for their records.	❍ Yes ❍ No
8.	Informed Consent Form was signed prior to any study-related procedures.	❍ Yes ❍ No
9.	Patient comprehension was assessed and deemed adequate by person obtaining consent.	❍ Yes ❍ No
10.	Protocol-defined acceptable contraception discussed.	❍ Yes ❍ No ❍ N/A
	The patient's current contraceptive method includes:	
11.	Anticipated expenses and patient responsibility for expenses were discussed.	❍ Yes ❍ No
12.	Patient verbalized their understanding of her responsibilities while enrolled in this study.	❍ Yes ❍ No
13.	Possible side-effects of Investigational Product(s) and/or Therapy were discussed in detail with the patient.	❍ Yes ❍ No
	Patient wishes to pursue treatment on trial:	

14.	Investigator signature was obtained on original Informed Consent Form (if required).	❍ Yes ❍ No ❍ N/A
15.	Were there optional selections to be offeredwithin the MAIN ICF?	❍ Yes ❍ No
	If 'Yes', did patient consent?	❍ Yes ❍ No
	If 'Yes', provide details (Biomarkers, Tissue, Records, Treatment Beyond Progression):	
16.	Was a SEPARATE optionalconsent form offered?	❍ Yes ❍ No
	If 'Yes', did patient consent?	❍ Yes ❍ No
	Title of optional consent form:	
	IRB Date Stamp/Version of Optional Consent:	
17.	Has this consent been evaluated by another research team member for the necessary quality check?	❍ Yes ❍ No
18.	Has patient been givenrequired identification cards?	❍ Yes ❍ No

Narrative Note

At the request of:	
The patient was consulted for study:	
Study title:	

The informed consent form was presented to the patient and she/he was givenample time to review it. All questions were answeredto her/his satisfactionwith Investigator available at all times for further clarification if needed. The voluntarynature of clinical trial participation was discussed, and the patient verbalized understanding. She/he signed consent with Clinical Research Coordinator present and was given a copy for her/his records.

IRB Date Stamp / Version of Main Informed Consent Form:	

My Name:	
My Role:	

Patient Name:	**DOB:**	**Site:**
Study Name:	**MD:**	
Screening #:	**Randomization #:**	
Centricity VIPStatus:	**NCT #:**	

Enrollment			
Screening date:		**Registration date with sponsor:**	
Randomized date:		**Arm randomized to:**	
Treatment start date:		**Optional consents:**	
Miscellaneous notes:		**Central scan review due at progression:**	
Current Visit			
Encounter Date:		**Nurse:**	
Cycle:	**Day:**	**Week:**	**Follow Up:**
Miscellaneous notes:			
Bill to Research this Visit (Please only list procedures that have already been completed)			
☐ **Labs** (list specifically)			
☐ **EKG**			
☐ **Hours of infusion**	**Planned:**	**Unplanned:**	
☐ **ECHO/MUGA**	**Location completed:**	**Type:**	**Date:**
☐ **Biopsy**	**Location completed:**	**Type:**	**Date:**
Scans	**Contrast:**	**Body site:**	**Type:**	**Date:**
☐ **SAE** (since last visit)	**Term:**	**Date:**	
☐ **Other:**			
Next Visit			
Next visit date:		**Next visit type:**	
EKG needed:	**Central lab kit needed:**	**Tablet needed:**	
Due for scans:	**Location of test:**	**Date:**	
Tissue collection needed:	**Location of procedure:**	**Date:**	
Miscellaneous notes:			

Off Study Treatment	
Date patient came off study treatment:	**Last date patient received study drug:**
Reason off study treatment: ☐ Toxicity ☐ Withdrawal ☐ Completed Cycles ☐ PD ☐ SAE ☐ MD Choice ☐ Patient Choice ☐ Death ☐ Other:	**Withdrawal:** ☐ Complete Consent – No more f/u ☐ Can follow via Phone & Medical Records ☐ Other:
Death is due to: ☐ Study drug ☐ Disease Progression ☐ SAE ☐ Other:	
Date of death:	**Screen fail due to:**
Miscellaneous notes:	

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. **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.	**R K B**

<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 rowspan="2">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: