Johns Hopkins University

A GUIDE FOR CLINICAL RESEARCH COORDINATOR MANAGEMENT AND SUPPORT

by
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Abstract

Research faculty who procure extramural funding need departmental support to satisfy the demands of conducting clinical research trials. The growing complexities, regulations, and ethical requirements of clinical research can be arduous. This may discourage faculty who have minimal protected time for research due to clinical and/or training obligations. Often research faculty are unaware of the support a highly qualified Clinical Research Coordinator (CRC) can provide. Retaining highly qualified CRCs has become difficult as the role has become more extensive and often leads to burnout.

This project involves the development of a guide to assist Principal Investigators in managing and supporting Clinical Research Coordinators (CRCs). The guide is an easy to follow, comprehensive resource that provides information on hiring, training, workload management, and helpful tips on professional development and performance evaluation, based on research and the author's experience as a CRC and assistant director of research for over 25 years.

Acknowledgments

For my parents, Andrew and Shelley Ryal, who have provided unfailing love and support my entire life. To my children, David and Ashley McMullen, who reassure and inspire me every day. Thank you to my husband, James Jackson III, for being my rock. Much gratitude to the beloved Dr. William T. Shearer, my stalwart mentor who sparked my passion for clinical research, and his loving wife Lynn Des Prez, for her continued encouragement. Above all, my Lord and Savior Jesus Christ, my source of hope and strength.

Table of Contents

Abstract ii
Acknowledgments iii
Table of Contents iv
Glossary vi
Abbreviations vii
Chapter 1. Introduction 1
1.1. Background 1
1.2. Statement of the Problem 2
Chapter 2. Review of Literature 5
2.1. Overview of Literature Review 5
2.2. Details of Review 5
2.2.1. Journal Articles 5
2.3. Applicability of Literature Review 7
Chapter 3: Need Assessment 8
3.1. Establishing the Need for a Guide 8
3.2. Metrics 8
3.3. Sources 9
3.4. Committee 9
3.4.1 Role of Committee in Project 9
Chapter 4: Project Description 10
4.1. Project Elements 10
Chapter 5: Methodology 11
5.1. Methodology Overview 11
5.2 Project Design and Discussion 11
5.2.1 Talent Selection 12
5.2.2 Orientation of the CRC Once Hired 12
5.2.3 Retention of the CRC 14
5.2.4 Workload Management 15
5.2.5 Evaluation and Feedback 15

5.2.6. Handing Over of the CRC Project 16
Chapter 6: Project Results and Discussion 17
6.1. Project Result 17
Chapter 7: Recommendations and Discussion 18
7.1. Recommendation 1: Ensure the guide is accessible 18
7.2 Recommendation 2: Updates and revisions 18
7.3 Discussion 18
Chapter 8: Conclusion 19
Bibliography 20
Appendix 1: Guide for Clinical Research Coordinator Management 22

Glossary

Clinical Research. Research involving human subjects or material of human origins such as tissues, specimens, and data.

Clinical Trial. A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.[1]

High Impact Communication. Clearly and succinctly conveying information and ideas to individuals and groups in a variety of situations; communicating in a focused and compelling way that drives others' thoughts and actions.

Emotional Intelligence. Establishing and sustaining trusting relationships by accurately perceiving and interpreting one's own and others' emotions and behavior in the context of the political environment; leveraging insights to effectively manage one's responses and reactions.

Good Clinical Practice. A standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that assures that the data and reported results are credible, accurate and that the rights, integrity, and confidentiality of trial subjects are protected.[2]

SMART Objectives. S.M.A.R.T. is an acronym used to guide the development of measurable goals. Each objective should be: Specific, Measurable, Achievable, Relevant, and Time oriented.

Translational Research. The process of turning observations in the laboratory, clinic, and community into interventions that improve the health of individuals and the public.

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[1] "NIH, National Institute of Allergy & Infectious Disease (NIAID)." *Rules and Policies for Clinical Research*. Last modified July 18, 2018.https://www.niaid.nih.gov/research/clinical-research

[2] "Good Clinical Practice Network." *ICH GCP / Good Clinical Practice*. https://ichgcp.net/.

Abbreviations

ACRP	Association of Clinical Research Professionals
BCM	Baylor College of Medicine
CRC	Clinical Research Coordinators
CTU	Clinical Trials Unit
GCP	Good Clinical Practice
IAR	Immunology Allergy & Retrovirology
IRB	Investigative Review Board
MGMA	Medical Group Management Association
NCRR	National Center for Research Resources
NCURA	National Council of University Research Administrators
NIH	National Institutes of Health
PHACS	Pediatric HIV/AIDS Cohort Study
PI	Principal Investigator
SOCRA	Society of Clinical Research Administrators

Chapter 1. Introduction

1.1. Background

The Departments of Immunology Allergy Retrovirology (IAR) and Rheumatology, at Texas Children's Hospital, are affiliated with Baylor College of Medicine (BCM), Department of Pediatrics. In 2012, several clinical research programs were initiated in the areas of food allergy, immunogenetics, HIV/AIDS, primary immune deficiency disorders, and rheumatologic disorders. The two departments started with four Clinical Research Coordinators (CRCs) but quickly expanded to 16 with one Assistant Director of Research providing oversight.

The coordinators worked directly with faculty Principal Investigators (PIs) who were new to sponsored research and/or unfamiliar with managing and supporting CRCs. Several of the PIs attempted to conduct trials without a coordinator or by utilizing the institution's central resource that was either too costly or unable to meet projected timelines. There was also the concern of high CRC turnover, within a national network, affiliated with the HIV/AIDS program.

For these reasons, this author decided that developing a CRC management guide would be a good resource for faculty PIs in the IAR and Rheumatology departments. The guide would also be a useful tool for other departments within Texas Children's Hospital, Baylor College of Medicine, and affiliated networks. In addition to training and orientation, this guide would provide helpful information regarding talent selection, orientation, retention, workload management, evaluation, and transition.

1.2. Statement of the Problem

PIs are not always familiar with the training and development required for a CRC to successfully implement clinical research trials. Once the CRC is fully trained it is another matter to make sure there is a balance between meeting enrollment targets and satisfactory performance.

There is also a need for PIs to understand the kind of support the CRCs need in to meet the study responsibilities that are placed on them. As protocols are becoming more complex and the roles of the CRCs are more extensive, the added burden may negatively affect their performance. Adequate training and sustained support are important to abate mistakes, burnout, and CRC turnover.

1.3. Project Question

The main question is how can the researcher of this project bridge the gap between the knowledge and understanding a PI needs to successfully manage and support CRCs who play a pivotal role in the overall success of study conduct, study outcomes, research subject safety, and data integrity.

1.4. Project Objectives

The primary objective of this project is to create a resource for PIs that guides in the successful management and support of CRCs from the time they are hired to the time they transition to new employment opportunities or retire. The secondary objective is to ensure PIs in the IAR and Rheumatology departments can continue to procure research funding by showing sponsors they can conduct quality research, on time, and reach enrollment targets. According to Holly Zink, a measure or important predictor of faculty research productivity are individual attributes combined with institutional attributes, such

as support systems and administrative assistance.[3] The combination of a faculty researcher with attributes such as emotional intelligence and high impact communication skills along with a highly qualified and motivated CRC are paramount.

Also, a successful research program could elevate the IAR and Rheumatology departments' reputation at the community, national, regional, and international levels.[4] This would increase income-generating capacities by attracting future faculty with a strong interest in medical research, ensuring the future success of the departments.[5]

1.5. Significance

The author of this project understands the stress CRCs face between expanding workloads and the continued effort to meet the demands of the PI(s). The CRC may not always have the confidence to express the need for more help and/or support. Although the CRC may find the work fulfilling both professionally and personally, the thought of having to face the consequences of making an error may cause the CRC to leave the position. To find and properly train a replacement, would cost the department valuable time and money.

According to the Medical Group Management Association (MGMA), "The cost of replacing an employee is 50% to 150% of the annual salary for that position, therefore, it can cost a medical practice from $25,000 to $75,000 to replace an employee

[3] Holly R. Zink. 2018. "Department-Centered Research Administration: Building a General Research Administrative Support Program (GRASP)." *Research Management Review* 23, no.1. https://www.ncura.edu/portals/0/docs/rmr/2018/v23_n_1_zink.pdf
[4] Ibid.
[5] Ibid.

with a yearly salary of $50,000." [6] This includes the cost of recruiting, hiring, training, and productivity lost during the new employee's first 6 months.[7]

BCM research faculty are under pressure to procure funding as the institution does not look favorably upon unfunded research. With limited protected research time, faculty PIs must rely on the competence of highly qualified CRCs who can perform clinical research in compliance with regulatory guidelines and Good Clinical Practice (GCP). By having a management guide, the hope is the department will retain competent, motivated, and productive CRCs.

1.6. Exclusions and Limitations

The guide is not all-inclusive of CRC orientation requirements but it provides references to many other tools and manuals that are available within the department, BCM intranet, and the internet.

[6] "Effective Staff Management." 2008. *Journal of Oncology Practice* 4 (6): 305–9. https://doi.org/10.1200/JOP.0866501.
[7] Ibid.

Chapter 2. Review of Literature

2.1. Overview of Literature Review

The literature search was related to the management and support of CRCs using PubMed, Society of Clinical Research Associates (SOCRA), National Council of University Research Administrators (NCURA), and Google search engine. Attempts were made to locate similar examples of CRC management guides to provide a basis for this project. There were many articles, tools, and guides that provided information on CRC orientation. However, this author could not find anything similar to a guide that goes beyond the orientation phase of CRC support and development. Presentations from coordinators of the Pediatric HIV/AIDS Cohort Study (PHACS) network meetings have also provided information in developing content for the guide.

2.2. Details of Review

2.2.1. Journal Articles

The researcher was able to locate studies and journal articles about CRC hiring practices, job satisfaction as well as roles and responsibilities. The Research Coordinator Taskforce, implemented by the National Institutes of Health (NIH) National Center for Research Resources (NCRR) conducted two surveys. The results are summarized in "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."[8]

The survey on hiring practices shows that approximately 60% of CRC positions take an average of 3 - 6 months to fill.[9] The majority of CRCs are hired and managed by individual principal investigators or departments. The article also shows that 80% of the coordinators surveyed were scheduled to work 40-hour weeks. However, 42% reported working more than 40 hours, some as high as 50 hours per week. [10]

The total number of studies supported by the 1,574 CRC respondents was 9,842, with an individual coordinator supporting from 1 to 85 studies for 1 to 50 investigators. Regarding CRC satisfaction, more than 75% of CRCs described their work as both professionally and personally fulfilling, and 85% believe their job is an important aspect of the overall mission of their institution.[11] However, being overworked was reported as one of the top negative aspects of their job, and 15% listed burnout as a reason for leaving their job, while 17% reported a lack of career advancement.[12]

Several studies were cited and/or conducted by the authors of "The Invisible Hand in Clinical Research: The Study Coordinator's Critical Role in Human Subjects Protection."[13] The article spoke of studies that show adding a coordinator to a research

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[8] Lisa Speicher et al, "The Critical Need for Academic Health Centers to Assess the Training, Support, and Career Development Requirements of Clinical Research Coordinators: Recommendations from the Clinical and Translational Science Award Research Coordinator Taskforce," *Clinical Translational Science* 5, no. 6 (December 2012): 470 - 475, https://doi.org/10.1111/j.1752-8062.2012.00423.x
[9] Ibid.
[10] Ibid.
[11] Ibid.
[12] Ibid.
[13] Arlene Davis et al, "The Invisible Hand in Clinical Research: The Study Coordinator\s Critical Role in Human Subjects Protection," *Journal of Law, Medicine & Ethics* 30 (2002): 411-419,

team significantly improves subject recruitment numbers, enhances subject retention, and increases general study efficiency.

The authors conducted a focus group interview study to determine to what extent coordinators shape the ethical conduct of clinical research and how their workload affects the protection of subjects. Seven 90-minute focus groups with a total of 45 participants were conducted. The study concluded that "the study coordinator is the person with whom study participants interact the most, and the one most able to identify their needs and employ necessary procedural safeguards.[14]

The authors described the CRC as central to the PI, Investigational Review Boards (IRBs), study monitors, study staff, referral networks, subjects/families, clinics/departments, and other supervisors.[15] The CRC requires multiple skill sets that include the ability to advance research goals using a variety of research-related skills; psychosocial skills; communication skills; and complex organizational skills including managing the protocol, functioning as a team member, and coordinating outside units.[16]

2.3. Applicability of Literature Review

The literature review helps to establish the relevance of hiring and retaining a highly-skilled CRC. It also shows the potential for turnover when the needs of the CRC are not met or understood.

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[14] Arlene Davis, "The Invisible Hand"
[15] Ibid.
[16] Ibid.

Chapter 3: Need Assessment

3.1. Establishing the Need for a Guide

The author of this project has the background of a Clinical Research Nurse Coordinator and successfully managing a Clinical Trials Unit (CTU) for a combination of 25 years. Now that this author has been promoted to Assistant Director of Research, the coordinators must be managed by the PIs as is the case in most of the departments within Texas Children's Hospital and Baylor College of Medicine. The guide would be shared with PIs within the department and other departments within the institution.

The author of this project has been asked to guide other CTU's within an affiliated network, National Institutes of Health (NIH) sponsored Pediatric HIV/AIDS Cohort Study (PHACS)[17]. The CRC management and support guidance is provided on monthly leadership conference calls and annual network meetings held in Bethesda, Maryland. The guide would be given to the leadership of this network as a tool for current and future PIs and/or senior CRCs.

3.2. Metrics

There were no specific metrics used to evaluate the need for developing a guide. Instead, this project is a compilation of both the author's experience and other resources to guide in hiring, orienting, managing, evaluating, and transitioning CRCs.

[17] "Pediatric HIV/AIDS Cohort Study (PHACS)," National Institute of Child Health and Human Development, accessed December 2019, https://www.nichd.nih.gov/research/supported/phacs

3.3. Sources

The Department Chief, Director of Clinical and Translational Research, PI for the NIH sponsored HIV/AIDS research, PI for the Childhood Arthritis Rheumatology Research Alliance and the Practice Administrator are in support of and have all agreed that the guide would be a valuable resource provided by this author.

3.4. Committee

The main point of contact throughout the project was the Director of Clinical and Translational Research for the Food Allergy Program and the mentor for this project. The senior CRC for the Food Allergy research was a point of contact as well. In-person meetings were held along with email correspondence.

3.4.1 Role of Committee in Project

The role of the committee was to review the Guide and give feedback on the relevance of the material provided in each chapter based on the needs of the departments, then give final approval. Also, this committee will play a large role in the promotion and distribution of this guide to the faculty PI within the department.

Chapter 4: Project Description

4.1. Project Elements

This project involves the creation of a guide with a compilation of information, methods, and tools, created by this author, that new PI's and senior CRCs may use to hire, train, develop, and retain highly qualified CRCs. This guide provides information from the Texas Children's Hospital (TCH) intranet, Baylor College of Medicine (BCM) research resources, orientation methods, and tools from other institutions and articles.

Navigating the TCH and BCM intranet for information can be time-consuming and daunting. Whereas, this guide will be an easily accessible resource within the IAR and Rheumatology Departments. It provides the main guidance that is essential to creating a clinical research environment that is supportive of CRCs.

Chapter 5: Methodology

5.1. Methodology Overview

The approach to gathering content for the guide was to perform extensive research into existing policies/procedures, peer-reviewed articles, in addition to the author's 25 years of experience as a CRC and Clinical Trials Unit (CTU) coordinator. Articles on effective management and building a team culture provided great insight regarding retention as CRC turnover can be very costly and disruptive to the research program.

Peer-reviewed methods and validated tools provided by articles from the Society of Clinical Research Associates (SoCRA) and the National Cancer Institute (NCI) were thoroughly reviewed and deemed useful for managing CRC workloads. References to other resources such as departmental SOPs, BCM online training, and IRB policies were compiled for the convenience of having all the information in one document.

5.2 Project Design and Discussion

There are six essential elements in the project design: CRC Talent Selection, the orientation of the CRC once hired, CRC retention, managing the CRC workload, evaluation, and feedback of the CRC's performance, and transitioning the CRCs project to another research team member in the event of their resignation and/or retirement. These six elements cover the spectrum of the CRC's experience from the beginning to the end of service in the IAR and Rheumatology Departments.

5.2.1 Talent Selection

The Texas Children's Hospital (TCH), Human Resources Department, provides Success Profiles which are a collection of competencies needed for an employee to effectively perform his/her job. This author selected the major competencies that best fit the role of a CRC and incorporated them in the guide. These competencies can be used in the talent selection/hiring process and to provide performance expectations upfront as part of orientation.

A CRC must be able to connect with study participants, carry out key clinical, administrative, regulatory responsibilities, and be committed to the research project. Therefore, the following competencies were chosen: Interpersonal Sensitivity, Decision Making/Problem Solving, Planning and Organizing, Technical/Professional Knowledge and Skills, Work Standards, and Adaptability.

5.2.2 Orientation of the CRC Once Hired

The CRC orientation in this Guide is based on the National Institute of Allergy and Infectious Diseases (NIAID) rules and policies for clinical research.[18] The NIAID has developed research standards regarding Human Subject Protection (HSP) and Good Clinical Practice (GCP) to maximize and harmonize the quality of clinical research. The four NIAID standards include Clinical research development, review, conduct and oversight; Clinical research management; Training and education; and Quality assurance and quality control.[19]

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[18] "NIH, National Institute of Allergy & Infectious Disease (NIAID)." *Rules and Policies for Clinical Research*. Last modified July 18, 2018.https://www.niaid.nih.gov/research/clinical-research
[19] Ibid

A list of required research ethics training includes the Department of Health and Human Services (DHHS) Code of Federal Regulations (CFR) 45 CFR part 46, and the International Council for Harmonisation (ICH) Good Clinical Practice (GCP). BCM requires the CRC to complete an online course in Researcher Conflict of Interest (COI), and Health Information Privacy and Security (HIPS).

The IAR and Rheumatology Department-required BCM training include an Informed Consent Workshop, a Research Investigator Workshop, Lab Safety Training, and the International Air Transportation Association (IATA) Biological Shipping Online Training. The contact and registration information for each course is listed in the guide.

Protocol specific training includes a training tool, created by the author, with a checklist for the CRC and PI to follow. The CRC will review the protocol materials and attend sponsor training. The PI, or preceptor designated by the PI, will assess the CRC's understanding of critical Protocol Elements and Informed Consent. Then the CRC will meet with the Regulatory Coordinator to review and file compliance documentation. Once all items are checked off the PI will sign and date the checklist.

Out of all the orientation manuals reviewed by this author during the literature review, the Maine Medical Center Research Institute Orientation Manual for Clinical Research Coordinators provided the most detailed information.[20] It provided details on competencies related to ethics, protocol feasibility, and collaboration with other departments, study initiation, informed consent, protocol implementation, investigational

[20] "Orientation Manual for Clinical Research Coordinators. Maine Medical Center Research Institute." *Main Medical Center, Maine Health*. Last modified 2009. https://www.mmcri.org/deptPages/em/downloads/CRC_Orientation_Manual/CRC_Orientation_Manual.pdf .

drugs and/or devices, subject safety, financials, data entry, and study close-out. This author was able to enhance current orientation processes by incorporating essential details from the Maine Medical Manual but utilized it in a different format. Instead of the PI and/or designee having to sign 14 different approval documents, a signature is only required on one form.

5.2.3 Retention of the CRC

This guide contains invaluable information on methods used to reduce turn-over and retain highly qualified CRCs. This is especially important due to the extensive amount of time that it takes to train a CRC. By managing the workload, supporting professional development, and offering a work environment that provides work-life balance, job satisfaction is significantly improved. The guide gives information regarding professional development opportunities which would demonstrate an investment in the CRC's career and highlight their value within the research program. Examples include memberships with and/or certifications from the National Council of University Research Administrators (NCURA), SoCRA, and the Association of Clinical Research Professionals. Based on this author's literature review, flexible scheduling also promotes retention as it allows the CRC to schedule longer hours on some days and shorter hours on another to be able to take care of personal business, without having to use vacation pay.[21] There are suggestions on creative performance rewards such as a gift card for the

[21] "Effective Staff Management." *Journal of Oncology Practice* 4, no. 6 (2008): 305–309. Accessed November 11, 2019. http://ascopubs.org/doi/10.1200/JOP.0866501.

most enrollments in 6 months.[22] Another retention strategy is creating a culture of team support.

5.2.4 Workload Management

A CRC may have multiple research protocols that vary in complexity, several participants enrolled, preparation for study visits, and/or the amount of data abstraction to be completed. Before a PI decides to accept another research project it is in the best interest of the CRC to assess the current workload and then determine how much time and effort is needed for the new project. A validated tool used to measure the complexity of a protocol, provided in this guide, was obtained from an Association of Clinical Research Professionals (ACRP) magazine article. The tool is useful in assessing the CRC's workload capacity and to adequately staff a research program to decrease burnout.

Another option for the PI is creative staffing which is finding ways to offload some of the CRC's work burden by utilizing other staff members in the department or new hires. The Guide provides ideas and tips in this section.

5.2.5 Evaluation and Feedback

The guide provides a Performance Review tool, created by this author, with five SMART objectives designed specifically for a CRC. The objectives are specific, measurable, achievable, relevant, and time-oriented. Objective 1: Protocol Implementation evaluates the percentage of time study visits are scheduled within the appropriate time frame, completion of required tests and procedures, timely completion of data entry, query response time, and accuracy of the source documentation in the

[22] Ibid

electronic medical record (EMR). Objective 2: Planning and Organizing Study Visits evaluates how well the CRC communicates with the study participant as well as other key providers to reduce missed visits. Objective 3: Protocol Consent and Eligibility evaluates compliance with Federal Policy and the avoidance of protocol violations. Objective 4: Safety evaluates the CRC's ability to report Adverse Events, Serious Adverse Events, and Endpoints according to the protocol to avoid violations and deviations. Objective 5: Professional Development assesses both the timeliness of required training as well as the self-initiatives, based on a tier point system. There is guidance on how often feedback should be provided as well as provisions for performance rewards.

5.2.6. Handing Over of the CRC Project

Clinical Research Coordinator (CRC) turnover is not always caused by burnout. A CRC may leave due to career and/or life changes such as retirement. This guide provides a handover checklist for the PI to follow to smoothly transition the project to a new coordinator. This checklist includes the key element of notifying the research participants as soon as possible. This is done as a courtesy, especially for the participant who has bonded with that CRC. The CRC should introduce them to the new CRC if possible to help alleviate their potential anxiety and hopefully retain their participation in the study.[23] The checklist also includes any information about the participants that may be helpful as well as outstanding items that need to be followed upon.

[23] Krys. "Why Effective Handover in Clinical Trials Is Important." *Affinity Clinical Research Services*. Last modified June 23, 2016. https://affinityresearch.com.au/why-effective-handover-in-clinical-trials-is-important/.

Chapter 6: Project Results and Discussion

6.1. Project Result

The result of this project is the creation of a guide to assist Principal Investigators in the management and support of Clinical Research Coordinators. It is a one-stop resource with a vast amount of information that is succinct and easy to follow. It gives the Investigator insight into the extensive training and educational needs of a CRC. It shows a new PI the vast amount of details involved in conducting clinical trials.

The literature reviewed has acknowledged the value a highly qualified CRC brings to the successful implementation and conduct of a clinical trial. The guide provides helpful tips and tools on how to manage the CRC's workload, thus preventing burnout. It shows how to effectively communicate expectations, as well as how to promote job satisfaction.

Based on the author's research and experience, the CRC Training Tool and the Protocol Feasibility Form were created and are provided in the appendix guide. The tools may apply to most protocols or they can be customized. The guide has been reviewed and approved by the Director of Clinical Research for the Food Allergy Program, whose comments and recommendations were incorporated in the final version.

Chapter 7: Recommendations and Discussion

7.1. Recommendation 1: Ensure the guide is accessible

The CRC Management Guide should be readily accessible to Investigators and senior CRCs both electronically as well as by hard copy. The electronic copy may be filed on the IAR BCM website. The Guide will be especially useful to new PIs as it will provide insight into the conduct of a clinical research trial.

The Guide should also be shared with others within the institution such as the BCM Sponsored Program Office (SPO) as they have a wide outreach to PIs, with the disclaimer that it was developed based on the needs of the IAR department. It may also be shared with fellow PIs within sponsored networks.

7.2 Recommendation 2: Updates and revisions

A biennial review is recommended to ensure information is up to date, the hyperlinks continue to work, and contact information is correct. Also, make sure recipients outside of the IAR department understand they are free to revise, customize, and/or update their copy of the guide to apply it to their specific needs.

7.3 Discussion

Conducting clinical research trials has become more complex and heavy with regulatory requirements. This can be discouraging to Investigators who are often physicians with minimal protected research time. Besides, most PI's are unaware of the benefit of having a highly qualified CRC. Using this guide as a resource will provide the help many PIs need to successfully conduct clinical trials.

Chapter 8: Conclusion

The conduct and implementation of clinical research require meticulous attention to detail, especially in the area of regulatory compliance. Noncompliance may result in the loss of grant funds, create a negative impact on the reputation of the PI as well as the institution, and hinder the procurement of future funds. Although the PI is ultimately responsible for all activities conducted at his/her site, a highly qualified CRC can significantly make a difference in the success of a research program.

In the experience of the author, there are gaps in knowledge of, not only what constitutes a highly qualified CRC, but how to keep them motivated to do the tedious work required of them. Also, it takes a significant amount of time for the PI to gather a minimal amount of references, tools, and information from multiple sources. Therefore, the experience of developing this guide has been extremely gratifying. The thought of this resource contributing to excellent clinical research that paves the way for new treatments and cures that can be delivered to patients quickly in the US and abroad is the ultimate reward.

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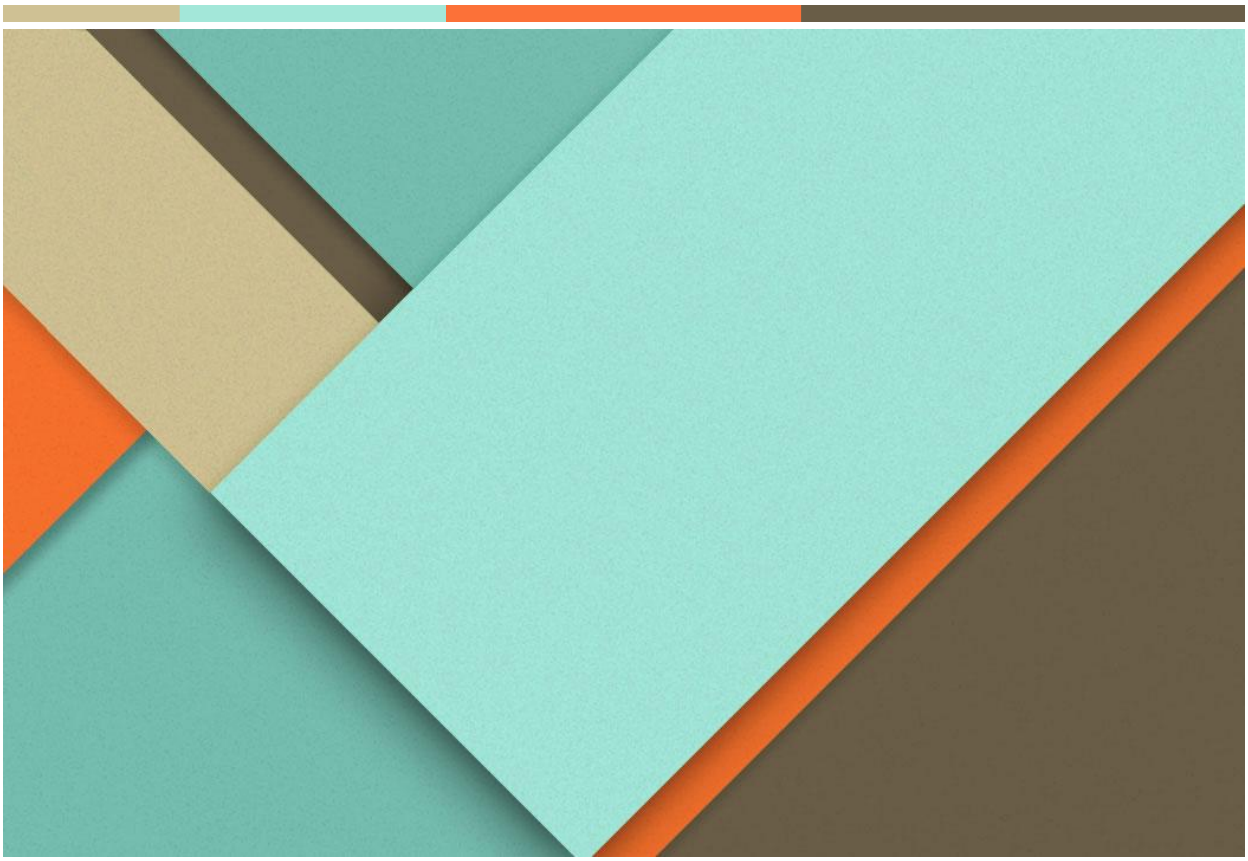
Appendix 1: Guide for Clinical Research Coordinator Management



A Guide for Clinical Research Coordinator Management and Support

2020 Edition

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Department of Rheumatology

Introduction

The guide intends to provide a single point of reference for Principal Investigators (PIs) who manage and support Clinical Research Coordinators (CRCs), at Baylor College of Medicine, Texas Children's Hospital, in the Departments of Immunology Allergy & Retrovirology (IAR) and Rheumatology. This guide will be a resource for PIs and/or Senior Coordinators who mentor and train the CRCs.

To have a successful clinical research program, it is key for departmental leadership to understand the needs of the CRC.[1] While the PI has overall responsibility for the conduct of a research clinical trial, it is the CRC who provides the fundamental structure necessary to organize, maintain, and administer the clinical trial program.[2] This guide also details the general knowledge and direction necessary for curating an environment conducive to the development and retention of highly qualified CRCs.

[1] Wendy Smith, et al. "A Survey of Clinical Research Coordinators in the Cooperative Group Setting of the American College of Radiology Imaging Network (ACRIN)." *Academic Radiology* 17, no. 11 (July 22, 2010): 1449–54. https://doi.org/10.1016/j.acra.2010.06.002.
[2] Ibid.

Table of Contents

Chapter 1: Talent Selection of a Clinical Research Coordinator.....26
1.1. Job Description Qualifications 27
1.1.1 Experience 28
1.1.3 Prior Training Specifications 29
1.2 The Interview Process 29
1.2.1 Planning the Interview 30
1.3 Competencies Listed on the Interview Feedback Form (IFF) 31
1.3.1. Interpersonal Sensitivity 32
1.3.3. Planning and Organizing 33
1.3.4. Technical/Professional Knowledge and Skills 33
1.3.5. Work Standards 34
1.3.6. Adaptability 34
Chapter 2: Orientation of CRC Once Hired.....35
2.1. Training: Federal, State and Institutional Regulations 35
2.1.1 Federal Regulations: Department of Health and Human Services (HHS) 35
2.1.2 Code of Federal Regulations (CFR) 36
2.1.3 The Food and Drug Administration (FDA) 36
2.1.4 International Council for Harmonisation (ICH) 37
2.1.4.1 Good Clinical Practice (GCP) 37
2.1.5 BCM Institutional Regulations 37
2.2. Protocol Specific Training 40
2.2.1. Essential Protocol Elements 41
2.2.1.1 Inclusion/Exclusion Criteria 41
2.2.1.2 Serious Adverse Event (SAE)/Adverse Event (AE) 42
2.2.1.3 Prohibited Medications While on Study 43
2.2.1.4 Study End Points 43
2.2.1.5 Schedule of Events 44

2.2.2 Informed Consent/Assent Process 44
2.2.3 Regulatory Assessment 47
2.3 Documentation and Essential Record Keeping Requirements 48
2.3.1 Informed Consent/Assent Form Documentation 48
2.3.2 Computerized Records/Electronic Medical Records 49
2.4. Data Entry and Record Retention 49
2.5 Study Close-Out 51
2.6 Site Monitoring Visits 51
2.7. Grants and Contracts Overview 52
2.8 Preparation for Site Selection of a New Protocol and Initiation Visit 53
2.8.1 Determination of Feasibility 53
2.8.2 Preparation for Site Initiation Visit 54
2.8.3 Collaboration with Other Ancillary or Specialty Staff 54
Chapter 3: Retention 57
3.1 Effective Communication 57
3.2 Professional Development 58
3.3 Improve Work Conditions 60
3.4. Performance Rewards 60
Chapter 4: Workload Management 62
4.1. Assessing Protocol Complexity 62
4.2. Creative Staffing 64
4.3. Cross-training 64
Chapter 5: Evaluation and Feedback 65
5.1. Performance Evaluation (PE) Tool 65
5.2. Feedback 66
Chapter 6: Effective Handover of Clinical Trials 67
6.1. Handing-Off Work Assignments 67
6.2. Research Participant Considerations 67

Glossary 69
Abbreviations 72
Appendix I: Interview Feedback Form (IFF).....73
Appendix II: CRC Protocol Training Tool 74
Appendix III: Clinical Trial Feasibility Form.....75
References 76
Biography.....79

Chapter 1: Talent Selection of a Clinical Research Coordinator

The success of a clinical research program relies heavily upon a Clinical Research Coordinator's (CRC's) ability to effectively manage day-to-day study-related activities. The challenge is finding the ideal CRC, especially given the complexity of most clinical trials. A well-designed talent selection process increases the chances of selecting the best candidate. This process involves developing an applicable job description, identifying and screening the pool of applicants, and implementing a well-planned and structured interview.[3]

1.1. Job Description Qualifications

Developing a job description requires collaboration with Human Resources. The job description should have details about the research the CRC will be working on. This will enable an astute applicant to prepare for the interview by proactively looking up information about the research project. The job description should list qualifications that describe some of the essential attributes of a CRC. Such qualifications should include experience, education, and training.

[3] Cyenthia Willis, et. al. "The Anatomy of a Great Clinical Research Coordinator." *The Association of Clinical Research Professionals (ACRP): Clinical Researcher*. Last modified August 14, 2018. https://acrpnet.org/2018/08/14/the-anatomy-of-a-great-clinical-research-coordinator/

1.1.1 Experience

A CRC who has at least one to two years of experience in consenting and enrolling human research participants is preferable. Prior clinical research experience of at least two years is required when the clinical trial involves an Investigational New Drug (IND). Studies with INDs require extensive knowledge of when and how to recognize and report Serious Adverse Events (SAEs) and Adverse Events (AEs) to ensure the safety of the research participant.

1.1.2 Education

At a minimum, a bachelor's degree in the life sciences and/or nursing fields will be the level of education needed to conduct the type of clinical trials performed in the Departments of Immunology Allergy & Retrovirology (IAR) and Rheumatology. An undergraduate degree in any other field may require at least two years of clinical research experience.

A certification in research administration is preferred, such as the Certified Clinical Research Professional (CCRP) certification obtained from the Society of Clinical Research Associate (SoCRA).[4] Another research organization that offers certifications is the Association of Clinical Research Professionals (ACRP).[5]

[4] "Society of Clinical Research Associates (SoCRA)." SoCRA, Accessed February 2020, https://www.socra.org/.
[5] "Association of Clinical Research Professionals (ACRP)." ACRP, Accessed February 2020, https://acrpnet.org/.

1.1.3 Prior Training Specifications

A very small percentage of entry to mid-level applicants have formal clinical research training. [6] Therefore, it is important to look for other attributes or competencies during the interview process. The recommended competencies are discussed in detail in section 1.3.

An applicant should be able to articulate prior training in ethics and regulatory compliance, specifically in Federal Policy for the Protection of Human Subjects, 45 CFR part 46.[7] This training should include general knowledge of and documentation requirements of informed consent, Investigative Review Board (IRB) reporting of protocol deviations, and reporting amendments or changes to the protocol.

1.2 The Interview Process

Make the interview matter by taking time to prepare for activities that must occur before, during, and after the interview. Before the interview, a select panel of interviewers should take the time to carefully review each resume. During the interview, a variety of behavior-based questions should be asked.[8] Behavioral-based questions can assess how the candidate handled various work

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[6] Wendy Smith, et al. "A Survey of Clinical Research Coordinators in the Cooperative Group Setting of the American College of Radiology Imaging Network (ACRIN)." *Academic Radiology* 17, no. 11 (July 22, 2010): 1449–54. https://doi.org/10.1016/j.acra.2010.06.002.

[7] "Department of Health & Human Services (DHHS)." *Office for Human Research Protections*. Last modified March 18, 2016. https://www.hhs.gov/ohrp/regulations-and-policy/regulations/common-rule/index.html

[8] Cyenthia Willis, et.al."The Anatomy of a Great Clinical Research Coordinator." *The Association of Clinical Research Professionals (ACRP): Clinical Researcher*. Last modified August 14, 2018. https://acrpnet.org/2018/08/14/the-anatomy-of-a-great-clinical-research-coordinator/

situations in the past. Examples of behavior-based questions that may assess problem solving, adaptability, and work standards include:

- When you worked on multiple projects how you did prioritize?
- Tell me about a time you were under a lot of pressure? How did you get through it?
- Describe a time when you found a problem and took the initiative to correct it rather than wait for someone else.
- Describe a time when you had to work with a difficult research participant/customer. How did you handle it?

After the interview, subjective feedback from each interviewer should be documented on the *Interview Feedback Form* (IFF) discussed in section 1.3.

1.2.1 Planning the Interview

It is optimal to have a panel of at least three experienced CRCs within the department who are familiar with the research project the candidate is applying for. The interview panel should review resumes and highlight the qualifications and/or attributes that meet the requirements for the job, thereby increasing the likelihood of selecting the top candidates.[9]

Determine which behavior-based questions will be asked during the interview and who will ask them. While one interviewer is asking the questions another should be writing down the answers. The interviewer

[9] Ibid

asking the questions should encourage the candidate to respond using the STAR method: (S) Situation- describe the situation in which the event took place; (T) Task- describe the given project or responsibility and the issue that had to be resolved; (A) Action- explain the action taken to resolve the problem; (R) Results- provide the outcome of the action that was taken.[10]

1.3 Competencies Listed on the Interview Feedback Form (IFF)

The Texas Children's Hospital (TCH), Human Resources Department, developed staff Success Profile Competencies that provide the definitions used on the *Interview Feedback Form* (Appendix I). Although competencies are used by TCH for the purpose of employee performance evaluations, they are useful in providing objective guidance in selecting a CRC.

The panelists should review the IFF and familiarize themselves with the list of competencies. There is a brief description of the competencies, a rating scale of 1 to 5, and a section for comments. The CRC candidate will not be selected solely based on the ratings on the feedback form. The feedback form will provide the basis for a discussion among the panelists and the PI prior to making the final selection.

[10] Allison Doyle. "Behavioral Based Job Interview Questions." *The Balance Careers*. Last modified October 22, 2019. https://www.thebalancecareers.com/behavioral-job-interview-questions-2059620.

The six competencies selected for the IFF are based on some of the qualities and skills that are necessary for a CRC to successfully conduct research. The competencies are 1) Interpersonal Sensitivity, 2) Decision Making/Problem Solving, 3) Planning and organizing, 4) Technical/Professional Knowledge and Skills, 5) Work Standards, and 6) Adaptability.[11]

1.3.1. Interpersonal Sensitivity

The CRC may encounter research participants from diverse backgrounds and/or socioeconomic status. It is to the advantage of the CRC to be able to build a rapport with potential study participants. During the screening/consenting process the CRC should be able to help the participant feel comfortable, assess whether or not the time is appropriate, and any needs the participants may have. If there are literacy concerns, the CRC must be able to approach them in a non-judgmental manner. The development of this initial relationship may lead to better adherence and retention throughout the study's lifecycle.[12]

1.3.2. Decision Making/Problem Solving

A CRC must anticipate problems and use good judgement when making decisions. For example, the CRC may need to promptly report any

[11] "Texas Children's Hospital." Institution. Department of Human Resources, Performance Management, April 2015.
[12] Cyenthia Willis, et. al. "The Anatomy of a Great Clinical Research Coordinator." *The Association of Clinical Research Professionals (ACRP): Clinical Researcher*. Last modified August 14, 2018. https://acrpnet.org/2018/08/14/the-anatomy-of-a-great-clinical-research-coordinator/

adverse events that are anticipated and/or unanticipated, usually within 24 to 48 hours for an SAE, based on protocol guidelines or the CRC may need to create solutions to problems that may potentially lead to loss of funding (i.e. not meeting enrollment targets, electronic data entry that is consistently late, tests and procedures that are consistently missed, etc.).[13]

1.3.3. Planning and Organizing

A key attribute of a successful study is the organizational capabilities of its CRC.[14] Disorganized and/or missing study records and regulatory documents may lead to protocol deviations, data that can't be analyzed, damage to the PI's reputation, and loss of funding. The CRC candidate should be able to give examples of how she/he maintained organization at a previous job (i.e. use of excel spreadsheets that are updated weekly, checklists, etc.)

1.3.4. Technical/Professional Knowledge and Skills

Leveraging technology allows the CRC to keep up with the current trends in clinical research. There are tremendous opportunities in social media, cloud computing, electronic consenting, direct data entry (DDE), telehealth study visits, etc., to drive efficiencies and reduce costs.[15] The CRC may also need to develop materials and tools, such as quick

[13] Ibid
[14] Ibid
[15] Priya Temkar. "Clinical Operations Generation next...The Age of Technology and Outsourcing" 6, no. 4 (December 2015): 175–178. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4640008/.

reference guides, to enhance study performance. Therefore, basic skills in Word, Excel, and PowerPoint are essential.

1.3.5. Work Standards

The CRC must have a strong set of values based on the ideals of discipline and hard work, staying motivated, and finishing tasks on time. For example, as the CRC abstracts and inputs data from many sources, she/he must ensure the data is timely, accurate, reliable, and valid.[16] Also, the CRC must ensure Good Clinical Practice is adhered to even when faced with deadlines and the pressure to meet certain targets. A high-principled CRC will self-impose work standards of excellence rather than having standards imposed and assumes a leadership role.[17]

1.3.6. Adaptability

The CRC must remain composed when faced with challenging circumstances. There may be an instance where a study participant becomes angry and/ or she/he is challenged with the addition of a complex protocol when the current workload is at a maximum. The CRC must be able to quickly come up with a solution and/or be able to communicate to the PI when there is a need for additional assistance.

[16] Texas Children's Hospital Institution. Department of Human Resources, Performance Management, April 2015
[17] Ibid

Chapter 2: Orientation of CRC Once Hired

The process of training and onboarding a new CRC may take up to 6 months. It is in the best interest of the clinical research program and the CRC to ensure basic training is conducted before the CRC performs any study related activity. The basic training includes research ethics and regulatory compliance; protocol specific activities related to the informed consent process, eligibility, and participant safety; documentation; and data entry. The later phase of training includes study closeout procedures, site monitoring visits, assistance with grants and contracts, and determination of protocol feasibility.

2.1. Training: Federal, State and Institutional Regulations

The first two weeks must be devoted to the ethics of conducting Human Subjects Research. The PI and/or Senior Coordinator, designated as the CRC preceptor, must set the tone that all research activity must be conducted with the highest ethical, legal, and scientific standards in accordance with the Federal, State, and Institutional regulatory requirements.[18] The CRC must be familiar with the purpose of each Federal Regulation and its associated agency, and how to access the BCM training.

2.1.1 Federal Regulations: Department of Health and Human Services (HHS)

[18] "Orientation Manual for Clinical Research Coordinators. Maine Medical Center Research Institute." *Main Medical Center, Maine Health*. Last modified 2009. https://www.mmcri.org/deptPages/em/downloads/CRC_Orientation_Manual/CRC_Orientation_Manual.pdf .

The Office of Human Research Protections (OHRP) provides guidance and maintains regulatory oversight in the protection of the rights, welfare and wellbeing of participants involved in research conducted or supported by the U.S. Department of HHS.[19]

2.1.2 Code of Federal Regulations (CFR)

The HHS Code of Federal Regulations, 45 CFR part 46, includes four subparts: Part A, the Federal Policy, also known as the "Common Rule"; Part B, additional protections for pregnant women, human fetuses, and neonates; Part C, additional protections for prisoners; and Part D additional protections for children.[20]

US. Dept. of HHS, Office for Human Research Protections website: https://www.hhs.gov/ohrp/regulations-and-policy/regulations/common-rule/index.html

2.1.3 The Food and Drug Administration (FDA)

The FDA is an HHS agency that regulates clinical investigations of products such as prescription and non-prescription drugs; biologics including vaccines for humans, blood and blood products, cellular and gene therapy products, tissue and tissue products, allergenics; and medical devices including heart pacemakers, surgical implants, and prosthetics.[21]

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[19] "Department of Health & Human Services (DHHS)." *Office for Human Research Protections*. Last modified March 18, 2016. https://www.hhs.gov/ohrp/regulations-and-policy/regulations/common-rule/index.html.

[20] Ibid

[21] "U.S. Food and Drug Administration." Last modified April 18, 2020. https://www.fda.gov/.

U.S. Food and Drug Administration website: https://www.fda.gov/

2.1.4 International Council for Harmonisation (ICH)

The ICH of Technical Requirements for Pharmaceuticals for Human Use responds to the global reach of drug development.[22] The ICH's mission is to overcome international Good Clinical Practice (GCP) inconsistencies throughout countries. Some of their guidelines are more stringent than the FDA.

2.1.4.1 Good Clinical Practice (GCP)

ICH-GCP is a harmonized standard that ensures the clinical trial data is credible, protects the rights, safety, and well-being of human research participants, minimizes human exposure to investigational products, improves quality of data, speeds up marketing of new drugs, and decreases the cost to sponsors and the public.[23]

International Council for Harmonisation website: https://www.ich.org/

2.1.5 BCM Institutional Regulations

Personnel at Baylor College of Medicine (BCM) involved in human research are expected to understand and apply their obligation to protect

[22] "International Council for Harmonisation." Last modified April 20, 2020. https://www.ich.org/.

[23] Vijayananthan, A, and O Nawawi. "The Importance of Good Clinical Practice Guidelines and Its Role in Clinical Trials." *Biomed Imaging Interv J.* 4, no. 1 (January 1, 2008). https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3097692/.

the rights and welfare of research participants, by following the BCM Human Research Protection Manual. [24]

The BCM Human Research Protection Manual can be found on the BCM intranet website:
https://intranet.bcm.edu/apps/research/oor/a_c/document/irb_manual.pdf

Baylor utilizes the Collaborative Institutional Training Initiative (CITI) online training. Documentation of current course certificates from CITI is required before institutional approval for conducting research. The CRC should complete courses under a Baylor College of Medicine CITI institutional profile where a minimum score of 80% is required for each course. Courses must be taken at the frequency indicated in Table 1.

As shown in Table 1, BCM requires the completion of the CITI Good Clinical Practice (GCP) course for research that involves FDA-regulated clinical trials to be completed every 3 years. Health Information Privacy and Security (HIPs, IPS) and Human Subject Research (HSR) must also be completed every 3 years and the Research Conflict of Interest (COI) must be completed every 4 years. To ship any biological specimens a certificate must be obtained from the BCM online course every 2 years.

[24] "Baylor College of Medicine Human Research Protection Manual," Last modified April 20, 2011. https://intranet.bcm.edu/apps/research/oor/a_c/document/irb_manual.pdf.

Table 1. BCM Required Regulatory Training

CITI Program Online Training: https://about.citiprogram.org/en/homepage/	
CITI Course Name	**Frequency**
Good Clinical Practice (GCP) *Required for individuals conducting FDA-regulated clinical trials*	Every 3 years
Researcher Conflict of Interest (COI)	Every 4 years
Health Information Privacy and Security (HIPS)	Every 3 years
Human Subjects Research (HSR) - Biomedical Research Basic & Refresher *Refresher module only required every three years*	Every 3 years
Shipping Biological Specimens *Required for CRCs who handle or ship biological specimens including human blood and tissue.* *The BCM Office of Environmental Safety (OES) IATA training certificate is acceptable*	Every 2 years

Baylor also has a series of seminars, workshops, and other online training, all of which the CRC will need to attend including:

- **Informed Consent Workshop**: A 2-hour interactive workshop that provides an overview of Informed Consent and Assent processes in clinical research, provides familiarity with applicable regulations and requirements, discusses quality improvement and consent monitoring, and provides relevant contacts and resources.
  To register for the workshop please call 713-798-4223 or e-mail researchcomplianceservices@bcm.tmc.edu

- **Research Investigator Workshop**: This hands-on, practical workshop addresses a wide array of research issues and regulatory requirements, including fundamental topics such as a brief history of human subject research, applicable regulations, BCM IRB Procedures, Good Clinical Practices, recordkeeping, required IRB submissions, and how to navigate the Biomedical Research and Assurance Information Network (BRAIN), the BCM electronic IRB system. Includes tips for a smoother submission and approval process.

  Please contact Research Compliance Services (RCS) at researchcomplianceservices@bcm.edu for more information
- **International Air Transportation Association (IATA) Biological Shipping Online Training**: This covers the transport of Class 6.2 infectious substances (blood, other bodily specimens, etc.) and Class 9 miscellaneous substances (dry ice and genetically modified organisms), shipper's responsibilities, and penalties for noncompliance.

  For questions concerning accessing the Environmental Safety online training, please contact Rebecca Luke at 713-798-6651 or rms1@bcm.edu
- **Lab Blood borne Pathogen Training**: This training focuses on how pathogens like HIV, HBV, and HCV are transmitted and how to minimize the risk of exposure through universal precautions and the use of appropriate personal protective equipment (PPE).For questions concerning accessing the Environmental Safety online training, please contact Rebecca Luke at 713-798-6651 or rms1@bcm.edu

2.2. Protocol Specific Training

The PI or designated preceptor will use the *Protocol Specific Training Tool* (see Appendix II) as a guide. The training tool includes a review of protocol materials, training provided by the sponsor, essential protocol elements, the informed consent process, and regulatory documentation.

The CRC may independently review the protocol materials including, the latest version of the protocol, the manual of operating procedure (MOP), and the laboratory processing manual. The CRC may attend an online webinar or an in-person workshop provided by the sponsor when applicable. The next items listed on the training tool require a one-on-one conversation with the CRC to assess the level of understanding of the protocol.

2.2.1. Essential Protocol Elements

The CRC's understanding of the essential elements of the protocol reduces the risk of harm to the research participant. This includes the inclusion/exclusion criteria, SAEs, prohibited medications, study endpoints, and schedule of events.

2.2.1.1 Inclusion/Exclusion Criteria

It is of critical importance that the CRC understands the inclusion and exclusion criteria to determine who is eligible for the study and who is not. Enrolling someone who does not meet the eligibility criteria may lead to a major violation, or much worse, cause harm to the participant, such as giving someone a study drug, who has a disqualifying health condition.

2.2.1.2 Serious Adverse Event (SAE)/Adverse Event (AE)

When conducting clinical trials that involve treatment, the CRC must be aware of what the study considers an Adverse Event (AE), a Serious Adverse Event (SAE), when and how to notify the sponsor, and the correct form of documentation. The FDA, ICH, and GCP set forth safety monitoring and reporting responsibilities of sponsors and investigators.[25]

According to the FDA definition - an adverse event or suspected adverse reaction is considered "serious", if, in the view of the investigator, it results in any of the following outcomes:

- Death
- A life-threatening adverse event
- Inpatient hospitalization or prolongation of existing hospitalization
- A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions or a congenital anomaly/birth defect
- Important medical events that may not result in death, be life-threatening, or require hospitalizations may be

[25] "NIH, National Institute of Allergy & Infectious Disease (NIAID)." *Rules and Policies for Clinical Research*. Last modified July 18, 2018. https://www.niaid.nih.gov/research/clinical-research.

considered serious when, based upon appropriate medical judgement, they may jeopardize the patient or subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition.[26]

Any AE that meets a protocol-defined serious criterion must be submitted to the sponsor immediately (no more than 24 hours of site awareness).[27]

2.2.1.3 Prohibited Medications While on Study

When a treatment protocol has a list of prohibited medications that may cause drug-to-drug interactions with the study agent, the CRC must assess the participant's concomitant medications at screening, entry, and each study visit thereafter. The PI and sponsor must be notified immediately, if and when the CRC becomes aware of the participant taking any of these medications, to determine next steps.

2.2.1.4 Study End Points

The CRC must be aware of the endpoint or outcomes determined by the study to indicate whether the treatment is beneficial or showing signs of toxicity. This may be determined by clinical assessment or laboratory testing. If a laboratory test is

[26] Ibid
[27] Ibid

abnormal it may require repeating the test. If the test remains abnormal this may require taking the participant off study. That is why all safety labs must be checked within 24 hours of the blood draw and reviewed by the PI/Sub-I.

2.2.1.5 Schedule of Events

The schedule of events is a list of tests, procedures, and questionnaires that must be completed at different time points throughout the life of the study. The schedule provides specific time points or research visits in days, weeks, months and years. The CRC will need to create a checklist for each visit to ensure all study procedures and tests are performed. Every missed test and procedure will be considered a protocol deviation. When there is a protocol deviation a detailed explanation of the cause must be recorded in the participant's study record.

2.2.2 Informed Consent/Assent Process

Obtaining Informed Consent of human research participants before involving them in research is one of the protections provided under the HHS regulations at 45 CFR part 46. It is founded on the principle of respect for persons, as described in the Belmont Report.[28] The Informed Consent

[28] "Department of Health & Human Services (DHHS)." *Office for Human Research Protections*. Last modified March 18, 2016. https://www.hhs.gov/ohrp/regulations-and-policy/regulations/common-rule/index.html.

Process requires that participants, to the degree that they are capable, be allowed to know what is going to happen to them (or not) during the entire course of the study.[29]

The CRC must be familiar with the different requirements and/or restrictions for the vulnerable populations and those requiring special protections (infants, children, adolescents, and pregnant women) who are recruited in the IAR and Rheumatology departments. In the case of minors (children below the age of 18 years) a Legally Authorized Representative (LAR) must give consent. The BCM IRB will determine the age a child less than 18 must provide assent, by following the rules in 45 CFR part 46.408.[30] During the assent process, the CRC explains the study in language the minor may understand. The child must provide an affirmative answer in order to participate in the study.

The IRB may also determine if one or both parental signatures are required based on the risk category: 1) not involving greater than minimal risk, 2) greater than minimal risk with benefit, 3) greater than minimal risk with no benefit, 4) does not meet conditions of 1, 2, or 3 (45 CFR 46.404 to 46.407).

[29] Ibid
[30] "45 CFR 46, Department of Health & Human Services (DHHS)." *Office for Human Research Protections*. https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html.

The BCM IRB requires the signature of both parents for risk categories 3 and 4 unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal custody or responsibility for the care of the child.[31] Once the minor reaches the age of 18 years and is still enrolled in the study, he/she must re-consent as an adult.

Pregnant mothers may sign consent for themselves, unborn child and neonate if there is direct benefit to her and no greater than minimal risk to the fetus.[32] Consent of the pregnant mother and the father is required if research offers direct benefit only to the fetus. However, father's consent is not required if he is unavailable, incompetent, temporarily incapacitated, or the pregnancy resulted from rape or incest.[33]

An emancipated pregnant minor may be able to sign consent for herself and her baby as determined by the state law and the IRB. In the state of Texas a minor petitioning a court for emancipation must be a Texas resident, 17 years old (or 16 and living apart from one's parents), and able to support and manage one's own affairs.[34]

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[31]"Baylor College of Medicine Human Research Protection Manual," April 20, 2011. https://intranet.bcm.edu/apps/research/oor/a_c/document/irb_manual.pdf.
[32] Ibid
[33] Ibid
[34] "Find Law." *Texas Legal Ages Law*. https://statelaws.findlaw.com/texas-law/texas-legal-ages-laws.html.

Once the PI/preceptor has determined the CRC's understanding of the basic Federal and institutional guidelines of consenting, the CRC can move to the next phase of training which includes the observation of a study participant being consented on a study. Then the CRC must role-play consenting with the PI/preceptor.

Office of Human Research Protections (OHRP), 45 CFR 46 website: https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html

2.2.3 Regulatory Assessment

The CRC will meet with the Regulatory Coordinator (RC) and submit all training documentation. The RC will provide the CRC access to the protocol (s) in the Biomedical Research and Assurance Information Network (BRAIN) where the CRC will be instructed to always print the consent form in real-time before use. Printing in real-time rather than using a stored copy ensures the use of the most up-to-date consent form.

The RC will also have the CRC sign the protocol-specific Delegation of Duties Log (DodL). The DodL specifies the roles and responsibilities of all personnel who participate in the conduct of a study and is mandated by all sponsored trials. The sponsor will check to see if research staff are adequately trained in their assigned roles.

A standard NIH approved Delegation of Duties Log (DoDL) template can be found on the National Institute of Allergy and Infectious Disease website https://www.niaid.nih.gov/sites/default/files/Delegation-of-Duties-Log-Template.pdf

2.3 Documentation and Essential Record Keeping Requirements

To ensure the quality and integrity of research data, source documentation must be based on the **ALCOA** method: **A**ttributable- is it obvious who wrote it? **L**egible-can it be read? **C**ontemporaneous- is the information current and in the correct time frame? **O**riginal- is it a copy, has it been altered? **A**ccurate- are conflicting data recorded in other places?[35]

2.3.1 Informed Consent/Assent Form Documentation

The consent form should be signed and dated before any research-related procedures are conducted with a participant in a clinical trial. The process of obtaining consent should be documented in the research record and should include: the time, especially important when consent occurs on the same day as enrollment/ randomization; a description of the consent process to show that it was not coerced; information about the study including all available options and that it was spoken in a language understood by the participant; the participant was given adequate time to consider all options; questions were answered, and comprehension was assessed.[36]

When obtaining consent for a minor the documentation must show the consent of the person of legal authority and that the study was

[35] "NIH, National Institute of Allergy & Infectious Disease (NIAID)." *Rules and Policies for Clinical Research*. Last modified July 18, 2018. https://www.niaid.nih.gov/research/clinical-research.
[36] Ibid

explained in an age appropriate manner for a child who is in the age range mandated by the IRB to obtain assent. This may be in the form of a separate assent form and/or documented in the medical record as determined by the IRB and the sponsor.

The CRC must also document that he/she gave the participant a copy of the consent and place another copy in the medical record. The original consent form must be stored in a research file with limited access to the research staff only.

2.3.2 Computerized Records/Electronic Medical Records

Printouts retrieved from the electronic medical record (EMR) are considered copies and are not the original record.[37] The electronic data in the computer system is considered the original source. Therefore, the CRC must ensure that the electronic signature along with the date and time of execution is visible at the bottom of the printed document.

A letter from the institution or the PI must certify that the electronic signature in the computer system is intended to be the legally binding equivalent of the traditional handwritten signature.[38] The certification may be in the form of an institutional policy.

2.4. Data Entry and Record Retention

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[37] "NIH, National Institute of Allergy & Infectious Disease (NIAID)." *Division of AIDS (DAIDS) Clinical Site Implementation and Operations*. https://www.niaid.nih.gov/research/daids-clinical-site-implementation-operations.

[38] Ibid

The CRC must maintain and secure complete Case Report Forms (CRFs), data collection forms, or direct data entry, into the protocol-specific database, within 2 to 3 weeks of the participants' study visit. All data must be verifiable by the source documentation.[39]

The CRC must meet with the Data Coordinator weekly to ensure queries and delinquent data are addressed promptly. Before transmitting data with protected health information (PHI) to sponsor, IRB, and regulatory agencies all documentation must be de-identified.

Clinical research records are required by the HHS regulations 45 CFR 46.111(b) and must be retained for at least 3 years after completion of the research, including completion of data analysis.[40]

For research also subject to FDA IND regulations 21 CFR 312.62(c), the PI is required to retain research records, case histories, safety reports, final reports, and final disclosure reports and records of drug disposition. Case histories include case report forms and supporting data (e.g. signed and dated consent forms, medical records, doctor's progress notes, nurse's notes, and individual hospital records).[41]

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[39] "Orientation Manual for Clinical Research Coordinators. Maine Medical Center Research Institute." *Main Medical Center, Maine Health*. Last modified 2009. https://www.mmcri.org/deptPages/em/downloads/CRC_Orientation_Manual/CRC_Orientation_Manual.pdf

[40] "NIH, National Institute of Allergy & Infectious Disease (NIAID)." *Division of AIDS (DAIDS) Clinical Site Implementation and Operations*. https://www.niaid.nih.gov/research/daids-clinical-site-implementation-operations.

[41] Ibid

2.5 Study Close-Out

The CRC will coordinate close-out procedures according to the protocol. This may include contacting research participants with final information and/or instructions, transitioning them to a routine care provider, and/or making sure there are no gaps in access to medication.

The final disposition of remaining study supplies may need to be arranged, as well as notification of all team members including participating departments. The CRC may also assist the PI and the Grants and Contracts team with data needed for the Research Performance Progress Report (RPPR) due within 30 days following the grant end date.

The NIH RPPR Instruction Guide website:
https://grants.nih.gov/grants/rppr/rppr_instruction_guide.pdf

2.6 Site Monitoring Visits

Research sponsors generally contract with agencies to hire clinical site monitors who perform on-site and/or electronic review of source documentation, participant records, regulatory files, facilities, laboratories, and pharmacies. Although the PI is ultimately responsible for the overall preparation, inspection activities, and correction of deficiencies identified during the monitoring visit, the CRC is usually the main point of contact for the site monitor. [42]

[42]"NIH, National Institute of Allergy & Infectious Disease (NIAID)." *Division of AIDS (DAIDS) Clinical Site Implementation and Operations*. https://www.niaid.nih.gov/research/daids-clinical-site-implementation-operations.

The CRC must prepare for activities before, during, and after the site monitoring visit. Once the monitor has secured the visit date, the CRC must reserve adequate space for the monitor, notify all involved study personnel of the visit, and assure those study subject binders and original source documents are available for data verification. The CRC must also assure that all screening logs and signed informed consents are available.

During the monitoring visit, the CRC and the RC will greet the monitor, establish meeting times with the PI and other staff as needed, and schedule the debriefing. They will also be available during the entire visit to answer questions and retrieve additional records as needed. During the debriefing, the monitor should notify the site of any findings that he/she identified. The site PI may ask the monitor to provide relevant regulations to justify any of the findings that are questionable.

After the visit, the PI and the CRC must prepare answers for any and all findings noted during the visit. The final report must be carefully reviewed and a written response provided promptly, no later than the specified due date.

2.7. Grants and Contracts Overview

The Clinical Research Coordinator (CRC) works in partnership with the grants and contracts section of the IAR department. The CRC provides the clinical information that is necessary to accurately prepare the budget and build the protocol into the institution's electronic Clinical Trial Management System (CTMS).

The CRC will assist in preparing the budget by determining the amount of effort needed to perform tasks and procedures, the type and amount of supplies needed throughout the study, other departmental collaborations such as diagnostics, participant payments, and any other potential expenses. During the study, the CRC assists with the review and reconciliation of finance charges.

2.8 Preparation for Site Selection of a New Protocol and Initiation Visit

One of the more advanced responsibilities of the CRC is to help determine the feasibility of the site's participation in a new protocol. The CRC can provide invaluable insight into the site's capacity to conduct the study safely and sufficiently. Once the PI decides to participate the CRC starts the preparation for the site initiation visit (SIV).

2.8.1 Determination of Feasibility

A sponsor may contact the PI to determine interest in a protocol and to assess whether or not the site is capable of conducting the trial. Initially, the site may only receive a synopsis or draft version of the protocol. Therefore, it may be difficult to make an informed decision. The CRC may use the *Clinical Trial Feasibility Form* (Appendix III) to fill in the gaps and help guide the discussion with the PI and the sponsor.

The Clinical Trial Feasibility Form lists a series of questions that will help to determine if the department has the appropriate population to adequately enroll into the protocol, the appropriate department resources

(including staff) and what supplies, if applicable, are needed to conduct the study.

2.8.2 Preparation for Site Initiation Visit

Once the site has been selected to participate in the new research protocol, preparation for a Site Initiation Visit (SIV), sometimes referred to as Site Establishment Visit (SEV), must begin. The CRC becomes the main point of contact by the sponsor and the following items must occur:[43]

- Attend Investigator meetings and/or conference calls.
- Assist with the preparation and submission of regulatory documents.
- Arrange for receipt and storage of test articles and study supplies.
- Arrange for adequate supplies of required shipping materials.
- Train staff according to their respective roles.
- Document all training.
- Ensure appropriate staff are available for the SIV.

2.8.3 Collaboration with Other Ancillary or Specialty Staff [44]

The CRC should determine any other ancillary services needed to conduct the new protocol, determine training needs, and meet regularly to mitigate issues in real time. The most common services are as follows:

- Laboratory

[43] Ibid
[44] IBID

- Meets with a lab technician to review and plan the required activities.
- Provides Laboratory Procedures Manual or Chart
- Demonstrates required skills for processing samples
- Completes IATA hazardous materials shipping training

- Pharmacy
  - Meets with Investigational Pharmacy to review and plan required activities
  - Provide Pharmacist with a copy of protocol
  - Develops plan with Pharmacist for:
    - Delivery and storage of investigational drug
    - Dispensing
    - Emergency unblinding procedures
    - Drug accountability

- Data Coordinator
  - Review Case Report Forms (CRFs)
  - Determine CRFs that will be used as source documentation
  - Assist with database training when there is direct data entry (DDE)

- Clinical Research Center
  - Meet with manager to give a brief preview of the protocol
  - Provide a copy of the eligibility criteria, study events
  - Provide in-service to staff

- Other Sub-Specialty Divisions

- Provide sub-specialist a copy of protocol
- Review eligibility criteria and recruitment goals
- Discuss training requirements and study procedures
- Determine the need for study supplies
- Determine scheduling logistics

Chapter 3: Retention

The retention of highly qualified CRCs is especially important because of the time it takes to recruit, hire, and train a replacement. There may be a significant loss of productivity during this time which contributes to loss in revenue.[45] There are several mechanisms, other than increase in salary, that may enhance the level of job satisfaction for the CRC including, effective communication, opportunities for professional development, improving work conditions, performance rewards, and promoting a team culture.

3.1 Effective Communication

Engaging the CRC in the development of the goals and/or plans of the research program shows how much their input is valued. Plan frequent meetings to discuss enrollment targets, challenges, solutions, and the feasibility of taking on new protocols. The meetings should be weekly at the very least. Share the sponsor's site evaluation reports in a manner that is helpful, with the intent to improve performance.

[45] "Effective Staff Management." Journal of Oncology Practice4, no. 6 (2008): 305–309. Accessed November 11, 2019. http://ascopubs.org/doi/10.1200/JOP.0866501.

3.2 Professional Development

Investing in the professional development of the CRC is in the best interest of the clinical research program, as it strengthens their skill set and improves their ability to do their jobs as they develop and grow as a person.[46]

There are several premier professional organizations for clinical research professionals. They are listed here, with a few highlights of what each organization has to offer its members and shown in Table 2 with fees. The Society of Clinical Research Associates (SOCRA) provides high-quality education through workshops, conferences, quarterly journals, live webinars, and weekly newsletters.[47] SOCRA is also well known for its certification program. The Association of Clinical Research Professionals (ACRP) is leading the way in regards to innovations in the clinical research workforce by validating standards for professional competence.[48]

The National Council of University Research Administration (NCURA) is ideal for an advanced or more senior CRC. The "Research Management Review" is a scholarly journal of NCURA that deals with a broad range of issues affecting the administration of research and the research environment.[49] Also, scholarships are provided to support members who pursue graduate education in research

[46] Ibid
[47] "Society of Clinical Research Associates (SoCRA)." SoCRA. https://www.socra.org/
[48] "Association of Clinical Research Professionals (ACRP)." ACRP. https://acrpnet.org/
[49] "National Council of University Research." (NCURA). https://www.ncura.edu/

administration such as the MS in Research Administration course at Johns Hopkins University.

Encourage CRCs to pursue other development opportunities such as submitting an abstract to a research conference, attending local and institutional workshops. BCM conducts a monthly compliance workshop, Clinical Research Education (CreED), which offers updates and practical advice on research-related regulations, IRB procedures, and "hot" or commonly misinterpreted topics. The sessions are held in the Cullen building, room 187A, no registration is required. TCH, Research Administration holds a bi-monthly seminar, Clinical Research Education Workshop (CREW), held in Feigin Tower, first floor, Conference Room A.

Table 2. Professional Organization for Clinical Research Professionals

Organization	Membership Dues	Certification
Society of Clinical Research Professionals (SOCRA) www.socra.org	$75/yrs.	Certified Clinical Research Professional (CCRP) $350/every 3 yrs.
Association of Clinical Research Professionals (ACRP) www.acrpnet.org	$150/yr.	Certified Clinical Research Coordinator (CCRC) $435/initial $250/every 2 yrs.
National Council of University Research Administrators (NCURA) www.ncura.edu	$190/yr.	N/A

3.3 Improve Work Conditions

Meeting the needs of a CRC beyond the office may positively influence work performance and directly benefit the research program.[50] This can be done through flexible work schedules that promote work-life balance. The CRC may discuss a preferred work schedule with the PI that should be approved based on the needs of the research program and policies of the institution.

Work performance and productivity may also be affected by the office workspace. The PI should occasionally survey the needs, desires, and/or challenges the CRC may face within the work area and take them into consideration during the next budget cycle.

3.4. Performance Rewards

The Texas Children's Hospital, Human Resources (HR) department has a merit-based system tied to the performance evaluation (discussed in Chapter 5). Depending on the market, the merit rate may change from year to year. Therefore, the PI should find other incentives to award performance. Creative ideas may include, a gift card for a massage, lunch, tickets to a movie or play, and/or recognition at a department-wide Town Hall meeting.[51]

3.5. Develop a Team Culture

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[50]Gemma Reeves. "Building Culture, Leading People, Skills Shortage." *7 Ways to Reduce Employee Attrition*. Last modified 2018. https://www.zippia.com/employer/7-ways-reduce-employee-attrition/.

[51] "Effective Staff Management." *Journal of Oncology Practice* 4, no. 6 (2008): 305–309. Accessed November 11, 2019. http://ascopubs.org/doi/10.1200/JOP.0866501.

A team culture is where everyone works toward a common goal and feels empowered to do so.[52] Everyone must feel that they can contribute their ideas toward the goals/plans of the program in order to promote buy-in. This may be accomplished by engaging everyone to contribute to the mission and values of the research program.

Texas Children's Hospital (TCH), Learning Academy, assist with developing a team culture through several courses offered throughout the year. The "i-Team" course teaches individual contributors how to tap into the power, purpose, and skills of being an effective team player. The course provides tools and skill practice around the 5Cs of teamwork: Connecting, Communicating, Collaborating, Conflict Resolution, and Commitment to action.

Scheduling activities outside of the work environment may also help to build trust by allowing team members an outlet to get to know one another on a personal level. A few examples of creative team-building exercises include an annual retreat at the home of the PI/CRC, exploring different restaurants on special occasions, attending sports events, or other ideas the team may suggest.

The TCH, HR, Learning Academy courses can be found on the SharePoint intranet under Classes and Training:
https://texaschildrens.sharepoint.com/sites/HR/SitePages/Classes-&-Training.aspx

[52] Ibid

Chapter 4: Workload Management

One of the top motives for a highly qualified CRC to leave a job is burn-out.[53] The role of the CRC evolves throughout the course of the research, as well as the complexities of clinical research protocols. Overburdening the CRC has the potential to cause delinquencies and gaps in research procedures leading to risks for the participant, the PI, as well as the institution.[54] A tool that measures the complexity of a protocol will help the PI understand the workload of the CRC.

4.1. Assessing Protocol Complexity

Assessing the complexity of a protocol may help determine the amount of effort needed to adequately staff and conduct a clinical trial. An example of a complexity tool with a scoring matrix is shown in Table 3. Each study element is assigned a point of 1 to 3 based on no, minimal, moderate, or maximum effort.

The study elements in the complexity tool include the experience of the PI, study recruitment, target enrollment, inclusion/exclusion criteria, informed consent process, screening procedures/visit, randomization/baseline visit, amount of personnel required outside of study team, and follow-up visit procedures. This

[53]Lisa A.Speicher, , Gregg Fromell, Sue Avery, Donna Brassil, Lori Carlson, Erika Stevens, and Michele Toms. "The Critical Need for Academic Health Centers to Assess the Training, Support, and Career Development Requirements of Clinical Research Coordinators: Recommendations from the Clinical and Translational Science Award Research Coordinator Taskforce*." *Clinical and Translational Science* 5, no. 6 (2012): 470–475. Accessed November 11, 2019. http://doi.wiley.com/10.1111/j.1752-8062.2012.00423.x.

[54] Ibid

tool can be customized to include other study elements, based the protocol, such as data collection and site monitoring requirements, for example.

In the complexity tool shown below, after adding up all the study elements, the highest possible score is 30. The PI can translate this score into work effort projections when preparing the budget or assigning staff projects to ensure equitable workloads. If a CRC has several protocols with high scores, this should indicate the need for additional staff, the need to reassign trials and/or reallocate staff.

Table 3. Complexity Tool Example

Complexity Tool				
Study Element	No Effort	Minimal Effort (1 Point)	Moderate Effort (2 Points)	Maximum Effort (3 Points)
Active Scoring Elements				
PI expertise and experience with clinical research	N/A	Physician has been lead PI on several trials and has a clear understanding of responsibilities	Physician has been Sub-I on a study(s) and has enrolled and followed patients on a clinical trial	Physician has minimal research experience and/or requires an increased level of engagement
Study recruitment	N/A	Development of flyers or adding or other tools	Community outreach	Specialized recruitment efforts will be required
Target enrollment	0	<20	20 - 100	> 100
Inclusion/exclusion criteria	N/A	1 - 10 inclusion/exclusion criteria	11 - 20 inclusion/exclusion criteria	≥ 21 inclusion/exclusion criteria
Informed consent process (initial)	No informed consent	1 - 10 pages	11 - 19 pages	> 20 pages
Screening procedures for eligibility (post IFC)	0	1 - 5	6 - 10	> 10
Screening visit (length)	N/A	< 4 hours	4 - 8 hours	> 8 hours
Randomization/baseline visit (length)	N/A	< 4 hours	4 - 8 hours	> 8 hours
Personnel required other than the research team	N/A	Involves only the research team	Involves moderate number of different medical disciplines and staff	Involves high number of different medical disciplines and staff, requires more effort and coordination
Procedures needed after baseline/randomization to end of treatment (outside of procedures/drug)	0	1 - 10	11 - 20	≥ 21

Source: Adapted from Alexa Richie, DHSc; Dale Gamble, MHSc; Andrea Tavlarides, PhD; Carol Griffin. "Trial Complexity and Coordinator Capacity: The Development of a Complexity Tool." *Clinical Researcher* 33, no. 5 (May 14, 2019). https://acrpnet.org/2019/05/14/trial-complexity-and-coordinator-capacity-the-development-of-a-complexity-tool/.

4.2. Creative Staffing

The PI may have to look at other ways to off-load some of the work burden when hiring an additional CRC is not option due to budget constraints. Consider hiring a Research Assistant(s) to help with tasks such as, scheduling study visits, request medical records, abstract data, and administer questionnaires. Another option is a Quality Assurance/Quality (QA/QC) person to monitor the safety of participants, the accuracy of the data, informed consent compliance, and adherence to protocol treatment, through the duration of the clinical trial.

4.3. Cross-training

A critical component of any research program is cross coverage for vacations and/or sick time. The CRC and/or the research staff should not feel incapable of taking time off for fear that no one will be able to cover their work. A backup should always be determined during the initial assignment of the protocol. A back-up may be the PI, co-Investigator, sub-Investigator, another CRC, or Research Assistant (RA). If the RA is the back-up coverage should be kept to a minimum and with supervision.

Chapter 5: Evaluation and Feedback

On the day of hire, and at the beginning of each year a formal review of performance expectations/ objectives should be discussed and agreed upon. The expectations should be based on the CRC's job description. In addition to the job description, the PI should create a Performance Evaluation (PE) tool that aligns to the job description, using a template provided by the institution. The objectives on the PE tool should be clear, measurable, achievable, and relevant.

Following the discussion at the beginning of the year is the mid-year review, which allows the PI to look back over the last 6 months, assess whether or not the CRC is meeting expectations, make adjustments if needed, and/or provide more coaching. By the end of the year the CRC should know what to expect on the final evaluation. There should not be any surprises.

5.1. Performance Evaluation (PE) Tool

Examples of five basic performance objectives/milestones for a CRC:

1. Organizes research according to specific protocol guidelines
    - Study visits are conducted according to schedule of events
    - Visits are scheduled within the study window
    - Case Report Forms (CRFs) and/or data entry are completed on time
    - Data queries are answered within the required time frame
    - Source documentation is accurate and complete
2. Effective planning and preparing for study visits in order to:
    - Minimize missed visits

- Maximize retention of research participants
- Promote a positive experience during the research visit
- Coordinate with other services (Pharmacy, Clinical Research Center, etc.)

3. Human Subject Compliance
    - Participants are consented and re-consented according to GCP
    - Only eligible participants are enrolled into the study
    - Children under the age of 18 are assented according to Federal, local, and institutional guidelines
    - Consenting process and eligibility are adequately documented
4. Adverse/Serious Adverse Events and Study Endpoints
    - Identify and report any detrimental medical occurrences
    - Report hospitalizations/prolongation of existing hospitalizations
    - Report any life-threatening events and/or deaths
    - Understand and identify study requirements for discontinuing study treatment and/or study follow-up
5. Required Training
    - Remains up-to-date on regulatory compliance training
    - Institutional required training is up-to-date
    - License and/or certifications are renewed on time

5.2. Feedback

In addition to the formal evaluation process, it is necessary to provide timely and thoughtful feedback. Any criticism should be done respectfully and in private. Addressing issues early helps to keep problems from becoming harder to manage. Waiting until there are multiple issues to address can overwhelm the CRC. Most importantly, offer praise in public, and thank them for a job well done.

Chapter 6: Effective Handover of Clinical Trials

A process for effectively handing over a clinical trial(s) should be in place before a CRC's leave of absence (if possible), resignation, or retirement. This process will alleviate gaps in study procedures, deviations caused by noncompliance, and/or harm to the study participant.

6.1. Handing-Off Work Assignments

The CRC must ensure the research team has access to any study-related files that are stored electronically and/or hard copies. She/he must also inform the team of any files that were sent to an off-site storage facility. For long-term studies (> 3yrs) the CRC should provide a list of key contacts such as study affiliates who are in other departments, site monitors, sponsor project officers, and any other personnel who are not on the study team.

All outstanding queries, delinquent forms, SAE/AEs that have not been resolved, screening lists of study potentials, and an inventory of study supplies, are examples of the kind of things the CRC should review with the team/person taking over the study. The Investigational Pharmacy, Regulatory Coordinator, and Lab Technician must all be notified of the CRCs departure and allowed to address any outstanding concerns.

6.2. Research Participant Considerations

It is critical to consider the needs of the research participants in the hand-off process. In many cases, the participants become very attached to their CRC

and may consider it a significant loss when they leave. The participant should be notified by phone or in-person by the departing CRC, and when possible introduced to the new CRC. Reassuring the participant that they will remain in good hands may help to mitigate the loss of continued study participation.

The departing CRC should review the study visit windows so the team member(s) will know when the next visit is due and provide any tips/special circumstances with the participants and family members. Support and sensitivity must be provided to the CRC as this may be difficult for her/him as well. The CRC may feel the same sense of loss as the research participant(s).

Glossary

Adverse Event (AE). Any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the subject's participation in the research, whether or not considered related to the subject's participation in the research.[55]

Assent. A child's affirmative agreement to participate in research. Mere failure to object should not, absent of affirmative agreement, be construed as assent. (45 CFR §46.402(b) and 21 CFR §50.3(n))[56]

Belmont Report. Guidelines that identifies three basic ethical principles that address ethical issues arising from the conduct of biomedical and behavioral research involving human subject. The ethical principles include: *Respect for Persons, Beneficence,* and *Justice*.[57]

Clinical Research. Research conducted on participants, material, or data of human origin with an identifiable person as the source. Clinical research includes exploratory, behavioral, and observational studies.[58]

Good Clinical Practice. An international ethical and scientific quality standard for designing, conducting, recording, and reporting trials that involve the participation of human subjects. (ICH E6)[59]

Informed Consent Process. A process by which a participant voluntarily confirms his or her willingness to participate in a particular study after having been informed of all aspects of the trial that are relevant to the participant's decision to participate. (ICH E6)[60]

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[55] "NIH, National Institute of Allergy & Infectious Disease (NIAID)." *Rules and Policies for Clinical Research*. Last modified July 18, 2018. https://www.niaid.nih.gov/research/daids-clinical-research-glossary#g.
[56] Ibid
[57] "Belmont Report." *U.S. Department of Health and Human Services (HHS), Office for Human Research Protections (OHRP)*. Last modified March 15, 2016. https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html.
[58] "NIH, National Institute of Allergy & Infectious Disease (NIAID)."
[59] Ibid
[60] Ibid

Investigational Review Board (IRB). The board, committee, or other group formally designated by an institution to review, to approve the initiation of, and to conduct periodic review of research involving human subjects. The primary purpose of such review is to assure the protection of the rights and welfare of participants in research. IRB reviewing DHHS sponsored research must be registered with OHRP and identified on the institute FWA.[61]

Investigational New Drug (IND). A drug or biological product that is used in a clinical investigation.

Legally Authorized Representative (LAR). An individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research (45 CFR 46.102(c)). The issue as to who can be an LAR is determined by the laws of the jurisdiction in which the research is conducted (e.g., local or state law).[62]

Participant. A living individual about whom an investigator conducting research obtains:

(1) Data through intervention or interaction with the individual, or
(2) Identifiable private information. (45 CFR 46).

The terms "participant " and "subject" are deemed to be synonymous within NIH Division of AIDS policies. (DAIDS)[63]

Principal Investigator (PI). The qualified person designated by the applicant institution to direct the funded research program. PIs oversee the scientific and technical aspects of an award and the day-to-day management of the research.[64]

Protocol Deviation/Violation. An unplanned excursion from the protocol that is not implemented or intended as a systematic change. Protocol deviation is also used to refer to any other, unplanned instance(s) of protocol noncompliance. For example, situations in which the investigator failed to perform tests or examinations as required by the protocol

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[61] Ibid
[62] "45 CFR 46, Department of Health & Human Services (DHHS)." *Office for Human Research Protections*. https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html.
[63]"NIH, National Institute of Allergy & Infectious Disease (NIAID)."
[64] Ibid.

or failures on the part of study subjects to complete scheduled visits as required by the protocol, would be considered protocol deviations.[65]

Serious Adverse Event (SAE). Any untoward medical occurrence that at any dose results in death, is life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/incapacity, or is a congenital anomaly/birth defect. This includes important medical events that may not be immediately life-threatening or result in death or hospitalization but may jeopardize the patient or may require intervention to prevent one of the outcomes listed in the definition above. (ICH E6 and E2A)[66]

[65] Ibid
[66] Ibid

Abbreviations

ACRP	Association of Clinical Research Professionals
AE	Adverse Event
ALCOA	Attributable, Legible, Contemporaneous, Original, Accurate
BRAIN	Biomedical Research and Assurance Information Network
CCRP	Certified Clinical Research Professional
CITI	Collaborative Institutional Training Initiative
CoI	Conflict of Interest
CRC	Clinical Research Coordinator
CRF	Case Report Form
CTMS	Clinical Trial Management System
DDE	Direct Data Entry
DoDL	Delegation of Duties Log
EMR	Electronic Medical Record
GCP	Good Clinical Practice
HHS	Health and Human Services
IAR	Immunology Allergy & Retrovirology
IATA	International Air Transportation Association
ICH	International Council on Harmonisation
IFF	Interview Feedback Form
IND	Investigational New Drug
OES	Office of Environmental Safety
OHRP	Office of Human Research Protections
PI	Principal Investigator
SAE	Serious Adverse Event
RPPR	Research Performance Progress Report
SEV	Site Establishment Visit
SIV	Site Initiation Visit
SoCRA	Society of Clinical Research Associates
STAR	Situation, Task, Action, Result
TCH	Texas Children's Hospital

Appendix I: Interview Feedback Form (IFF)

Candidate **Interview Date**

Rating Scale

5 Much more than Acceptable (Significantly exceeds criteria for successfuljob performance/motivational fit)
4 More than Acceptable (Exceeds criteria for successful job performance/motivational fit)
3 Acceptable (Meets criteria for successful job performance/motivational fit)
2 Less than Acceptable (Generally does not meet criteria for successful job performance/motivational fit)
1 Much less than Acceptable (Significantly below criteria for successful job performance/motivational fit)

Assigned Targets	Rating	Comments
Interpersonal Sensitivity - Remain open to ideas; commits to understanding others; listens with empathy;interprets non-verbal communication; allocates time for others; calming and comforting presence.		
Decision Making/Problem Solving- Identifies issues, problems, and opportunities; generates alternatives; chooses appropriate actions; involves others.		
Planning and Organizing- Prioritizes; determines tasks and resources; schedules; leverages resources; stays focused.		
Technical / Professional Knowledge and Skills- Promotes and delivers evidence-based care for patients; leverages technology and appropriate software as an aid in planning and implementing job responsibilities.		
Work Standards- Sets high standards of performance for self; ensures high quality; takes responsibility; encourages others to take responsibility.		
Adaptability- Tries to understand changes; approaches change or newness positively; adjusts behavior.		

Appendix II: CRC Protocol Training Tool

Clinical Research Coordinator
Protocol Specific Training

Name _____

Protocol Name _____ Version # _____

	Date Completed	*Initials/Notes
Review of Protocol Materials ☐Current Version_____ ☐Manual of Operations (MOP) ☐Lab Processing Chart ☐Amendments/Clarifications ☐Other_____		
Sponsor Training ☐In-Person Workshop ☐Webinar ☐On-line Power Point ☐Other _____		
Protocol Key Elements ☐Inclusion/Exclusion ☐Study Objectives/Purpose ☐AE/SAE Reporting ☐Prohibited Medications ☐End Points ☐Schedule of Events ☐Other_____		
Informed Consent ☐Reviewed Site SOP ☐BRAIN IRB Access ☐Observed PI/Preceptor ☐Mock IC w. PI/Preceptor ☐Other _____		
Regulatory Documentation ☐CITI training ☐Protocol training ☐CV, signed, dated ☐Conflict of Interest (COI) ☐1572 FDA Form ☐Delegation of Duties Log ☐Other _____		

*Initials of PI/Preceptor

PI Name _____ Signature _____

Preceptor _____ Signature _____

Appendix III: Clinical Trial Feasibility Form

CLINICAL TRIAL FEASIBILITY FORM	
Principle Investigator	
Title of the Study	
Sponsor	

Enrollment Potential	Yes	No	N/A	Comment
1. Are there any competing trials ongoing within the department?				
1.a. If so, will there be a sufficient number of eligible participants for the				
1.b. Is there a plan to avoid research burden for the eligible				
2. If unsure of the potential subject population, search database or medical coding lists to determine the number of patients seen at site with a specific diagnosis code.				
3. Are the inclusion and exclusion criteria realistic. Consider if study includes treatment-naïve population?				
4. Determine if the trial requires too much of the study patients or volunteers: - in time or cost i.e. some studies include standard of care (SOC) or				
5. Are there extenuating circumstances that would adversely affect				
6. What is the expected screen failure ratio and will sponsor pay for unlimited screen fails?				
7. Will a patient stipend be in the sponsor's budget to cover subject cost to participate (mileage, parking, etc.)?				
8. Are vulnerable populations involved (children, prisoners, anyone with impaired decision-making capacity) that may require additional IRB and recruitment protections?				
9. Enrollment goals/milestones can be met: Specify number of participants/timeframe				

Departmental Resources	Yes	No	N/A	Comments
1. Are qualified staff available?				
2. If needed, is training available?				
3. Is the workload manageable?				
4. Does the PI have adequate time to devote to the protocol?				
5. Are additional specialists needed?				
6. Are study visits complex, presenting possible scheduling				
7. Case report forms (CRFs) and patient questionnaires reviewed if available and time required to complete assessed.				
8. Will the study involve after hours/ On-Call coverage or coming in off hours for enrollment?				
9. Are there adequate sub-investigators to assist PI with the trial?				
10. How often will the monitor visit?				
11. Are ancillary or specialty staff needed (pharmacy, labs,				

Supplies	Yes	No	N/A	Comments
1. What will the sponsor supply (CRFs, source documents, electronic consent template, packaged lab kits, pre-paid shipping, etc.)?				
2. Will electronic or remote data capture be used? If so, will sponsor provide hardware and training?				

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Biography

Chivon McMullen-Jackson obtained her Bachelor of Science in Nursing from Tennessee State University prior to completing her Master of Science in Research Administration at Johns Hopkins University. She is currently the Assistant Director of Research for the Departments of Immunology Allergy Retrovirology (IAR) and Rheumatology at Texas Children's Hospital, an affiliate of Baylor College of Medicine, Houston. She has been working for this institution since 1994. Job duties have included clinical care nurse, research nurse, and research nurse coordinator. For fifteen years, she coordinated the HIV/AIDS research, with a cumulative total of $15 million dollars in NIH funding.