



■ FOR LEARNING ■ FOR LISTENING ■ FOR LIFE

HIRING GUIDELINES

— *for* —

ENTRY LEVEL CLINICAL RESEARCH COORDINATORS™

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Executive Summary

Competency is defined as a combination of knowledge, skills, abilities and job attitude (KSAs) that are reflected in and observed in job performance¹. The Joint Task Force for Clinical Trial Competency (or JTF) has developed a framework including 8 competency domains for which all clinical trial professionals should be proficient in order to ensure safe, ethical and quality research standards². ACRP has been adapting these to create role specific guidelines which have endeavored to link the competencies to specific tasks that entry level through senior Clinical Research Coordinators (CRCs) should achieve in order to enhance their proficiency and advance in their careers³.

When it comes to hiring for roles in clinical research however (for which there are a growing number of clinical research-specific degree programs), these competency guidelines have some limitations. Namely, they presume detailed knowledge of clinical research, investigational product development and regulations, GCPs, study and site management, data management and informatics and more – content which an entry level candidate, with no prior clinical research experience would be unlikely to know. However, knowledge is only one part of the competency equation. Defining the skills/abilities and attitudes/behaviors that set someone up for success in a given role take on greater importance when it comes to developing hiring guidelines for entry level candidates.

This guidance document provides best practices from industry experts to assist with:

- Reducing job turnover by allowing sites to select Clinical Research Coordinator (CRC) candidates who will be more satisfied and successful in their role
- Guiding HR departments and hiring managers in the CRC candidate selection and assessment process
- Standardizing and professionalizing the career of CRCs

Background

Under the auspices of ACRP’s Workforce Innovation Steering Committee (WISC), a task force of diverse experts with experience in hiring, developing and managing CRCs, as well as those working directly in the role of a CRC was convened to develop these hiring guidelines. Following a systematic process to first prioritize key competencies, map these to KSA categories and then describe methods for how all of these attributes can be assessed during the hiring process, the task force has developed the following guidelines. Key references from the general HR literature were also considered^{4,5,6}. The draft guidelines were then reviewed by members of the WISC for additional input and recommendations.

The objectives of these guidelines are to help those who hire entry level CRCs better hone and prioritize their hiring process to focus on the competencies that are most predictive of success, particularly when candidates don’t come through one of the competency-based academic degree programs (where the requisite core knowledge aspects of clinical research are covered). The guidelines were developed recognizing that “entry level” candidates may include those with limited work experience (e.g., new graduates from a healthcare or life sciences degree), those with some work experience in a related field but brand new to research (e.g., certified medical assistant) or those transitioning from other careers (e.g., nurse or other allied health practitioner). Certainly, those candidates graduating from an academic program would have an advantage from the core knowledge perspective and some may come with practical hands-on experience which would be an added benefit. In addition, the task force recognized that the expectations will vary based on the type of institution for which the candidate is being hired (e.g., an entry level CRC working in a dedicated research center may vary from that of someone working in a large academic medical center). As such, these guidelines represent points of consideration that should be adapted to the candidate and the organization.

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Key KSAs for Entry Level CRCs

The following captures the spirit of KSAs that the task force representatives believe to be predictive of success in the role of a CRC. Depending on the organization and the specific roles and responsibilities of the CRC, some of the KSAs may be more important than others. For example, if the CRC will be routinely interacting with physicians or others in a position of authority, then the ability to stay calm under pressure may be prioritized over attention to detail for a CRC whose primary responsibilities may be focused more on regulatory and data management activities. Clearly not every candidate will possess all of these, but they provide a composite view of characteristics that can be assessed during the hiring and candidate selection process.

Knowledge

Medical terminology: Familiarity with basic medical terminology

Skills/Abilities

Attention to detail: The ability to demonstrate thoroughness and accuracy when accomplishing a task

Communication: Excellent verbal and written communication skills.

Connection and collaboration: The ability to establish rapport, create a relationship of trust and build collaborative relationships

Cool under pressure: The ability to stay calm in high pressure situations; the ability to stand up for themselves

Coordination: Strong organizational capabilities

Creativity: The ability to think outside the box when addressing problems and identifying solutions

Critical Thinking Skills: The ability to make reasoned judgments that are logical and well-thought out.

Customer Focused: Excellent customer service skills - including being skilled at good penmanship with clarity of writing

Empathy: The ability to understand and share the feelings of another

Flexibility and Adaptability: the ability to adapt to changing job demands and priorities; the ability to “switch gears” to meet different job demands

Maturity/Professionalism: The ability to respond to situations in an appropriate manner; behaving and knowing when to act according to the circumstances

Multi-tasker: The ability to effectively manage multiple activities. Alternatively, Single-tasking: the ability to accomplish more in less time through sustained focus

Self-Directed: The ability to show initiative, work autonomously, and to organize oneself

Team Player: The ability to work in and thrive within a team environment

Tech-savviness: The ability to navigate comfortably with different software and applications (e.g., EDC and EMR systems, MS Excel, MS Word, etc.)

Attitudes / Behaviors

Commitment: Demonstrates the attributes of commitment in terms of being willing to be challenged, seeking ways to overcome obstacles, and exceeding minimal expectations.

Curiosity: Demonstrates a willingness to learn and ask questions and pursue continuing education to excel in their role

Enthusiasm: Demonstrates a “can-do attitude”, is not fearful of trying new things; is resourceful in trying to find answers to questions

Humbleness: Demonstrates a willingness to acknowledge their

limitations or when they don't know something

Independence: The candidate demonstrates a desire and drive to work autonomously

Integrity: Demonstrates the qualities of being honest and having strong moral principles

Likes structure and organization: Generally speaking, the candidate prefers to work within this type of setting (e.g., a “baker” vs. a “chef”); Somewhat of a rule follower (balanced with above attributes of being able to be flexible)

How to Structure the Candidate Review Process

While some of the KSAs are more intangible in nature (e.g., integrity and maturity), for the most part the competencies can be assessed in a systematic way that provides both structure and objectivity during the candidate review process. Building on some general hiring best practices (5), the following are recommended.

Things to look for in reviewing cover letters and CVs:

WHAT TO LOOK FOR	WHAT IT SIGNIFIES <i>(or might indicate)</i>
<p>Educational Background:</p> <ul style="list-style-type: none">• Some suggest Life sciences or healthcare (Associate’s or Bachelor’s degree preferred).• Others have found that individuals with degrees in education or other backgrounds are also suitable for entry level roles	<p>Past experience working in high pressure situations or fast-paced environment (such as working for a senior executive or busy hospital unit or clinic)</p>
<p>Volunteer Work or paid work in services industry (e.g., food services, retail or other public facing business), health care industry (e.g., nurse’s assistant, medical assistant) or other sales roles (particularly if the coordinator will be playing a strong role in subject recruitment)</p>	<p>That the candidate has experience interacting with customers and would have had basic customer service training</p>

WHAT TO LOOK FOR	WHAT IT SIGNIFIES <i>(or might indicate)</i>
<p>Past experience working in high pressure situations or fast-paced environment (such as working for a senior executive or busy hospital unit or clinic)</p>	<p>That the candidate appreciates the demands of high-pressure situations and is more likely to have the ability to remain calm under pressure</p>
<p>Length of time in prior roles</p>	<p>Generally speaking, people stay in jobs longer if they have good relationships and if they have the ability to establish rapport with their peers</p>
<p>Work, school or volunteer activities that demonstrate they can / enjoy working in a team (e.g., participates in a team sport or social club)</p>	<p>The ability to work or thrive in a team environment.</p> <p>Note: if not readily identifiable in the CV this could be posed as an open-ended question</p>
<p>Typos, grammatical errors, general flow and organization of the CV / cover letter</p>	<p>A lack of attention to detail</p>
<p>Prior types of roles and experiences</p>	<p>Indicators that they can work in jobs that require them to be autonomous (e.g., someone with experience as a nurse would likely be used to this type of environment) as well as likelihood that they can analyze information and make a reasonable judgement</p>

WHAT TO LOOK FOR	WHAT IT SIGNIFIES <i>(or might indicate)</i>
Their hobbies and interests, extracurricular activities	More adventurous hobbies may indicate they are not fearful of trying new things; types of hobbies may indicate more team oriented vs. independent type of environments for which they are more comfortable. Do they seek leadership opportunities?
Ongoing continuing education or training beyond their basic educational background	Willingness to learn and grow in their careers; a willingness and commitment to improve and be challenged intellectually

Ways of approaching the interview/candidate assessment:

It goes without saying that all of the recommendations provided in these guidelines should be evaluated in the context of your institutional policies and with the input of your Human Resources (HR) experts. Nonetheless, the following are some considerations that our task force members have found helpful during the candidate interview and assessment process.

Who should be involved in the interview?

- The hiring manager
- Other team members including seasoned coordinators or other members of the research team who will be interacting with the potential new employee
- An “authoritative figure” (e.g., department head, hiring manager, physician or Principal Investigator [PI])

How long should you allocate for the interview?

- A suggested recommendation includes (although this depends on the type of organization in terms of how many and what type of staff to involve as well as how much time they may have available to allocate to interviewing potential candidates):

Approximately 45 minutes to 1 hour with the hiring manager

30 min with the PI and a team leader or other leadership (as appropriate for your organization)

Approximately 45 minutes to 1 hour with the team

- Consider having the candidate come in over the course of two different days to see how they present themselves over time
- Consider having them shadow another coordinator for some period of time so that

they can get a clear picture of the role. This allows them to assess whether they believe they would in fact be a good fit for the job, helps to determine how they interact with other members of the team as well as provide clarity on some of the competencies and characteristics necessary for success in the role

Note: Some sites have found it successful to have candidates come back on a day/time when there is a specific patient experience or physician/PI interaction vs. during the “down times” so that the team can gauge their level of comfort in the clinical setting. This would need to be done in compliance with appropriate patient privacy restrictions as per institutional policy.

How should we structure or approach the interview / live assessment of the candidate?

- Prioritize the questions and information you are trying to answer/gather and make sure they really count in terms of giving you useful information to make an informed decision
- Create an environment where they do most of the talking
- Consider having a PI or physician ask pointed questions to see how the candidate responds in more high-pressure situations with authoritative figures
- Take the candidate on a tour of the facility and see how they interact with others

What are some of the most informative behavioral interview questions we should ask?

BEHAVIORAL INTERVIEW QUESTIONS

WHAT TO LOOK FOR IN THE RESPONSES

Describe a high-pressure situation you have faced in the past and how you handled it

How have you, or would you handle, a situation where a lot of pressure is being placed on you?

How do you navigate corporate politics (describe an example)?

Answers such as “I stay motivated and concentrating on the end result helps me stay positive” vs. more generic responses such as “I don’t get stressed out” are more substantive

Give an example of how you structure your day (when you were working at a prior job or at school)

Describe a project that you have worked on and how you accomplished the work

With an add-on question of “how many others were involved and how did you interact with them or how did you leverage their skills”?

Examples of how they organize their work and use their time (i.e., good time management skills)

Do they take the initiative to find additional work during slow periods or down time?

Do they describe innovative ways of doing work more efficiently and effectively?

**BEHAVIORAL
INTERVIEW QUESTIONS**

What are the typical customer interactions you have in your current position?

Ask the candidate how they go about building rapport with their peers or patients (if they have that experience)

Give me an example of how you went above and beyond to provide great customer service in a prior job

What qualities do you think you developed from working in XYZ industry you mentioned on your CV? How do you think these qualities will apply to working with patients and research subjects?

**WHAT TO LOOK FOR
IN THE RESPONSES**

Look for their body language as indicators of good non-verbal communication and ability to establish rapport with you (e.g., leaning forward, uncrossed arms and legs, smiling, nodding, eye contact and asking open ended questions back to you)

Do you get a sense that they are skilled at developing rapport and/or demonstrate empathy in communicating to patients?

Do you get a sense that they are customer-focused, enthusiastic and assume personal responsibility for ensuring high customer satisfaction?

**BEHAVIORAL
INTERVIEW QUESTIONS**

Describe a situation where you worked with teams, disagreed with a team member, or led a team. How did you manage those interactions

Describe how teamwork (or lack of a high functioning team) can enhance or impact the workplace

Describe a time when a team failed or succeeded; what was your role in that situation? What contributed to the dysfunction of the team?

Describe a team project you've worked on – what was your role and how did the team work together to accomplish the goal?

Give me an example of a project or idea you've undertaken even though you knew it would not be popular with others on your team. How did things work out and what did you learn from the experience?

What does it mean to you to be a "team player" or what are the top 3 characteristics of a successful team in your view?

How would your current (or recent) coworkers and/or supervisor describe you? What do they like best about working with you and what are areas they have suggested that you could improve upon? What bothers you most about other people in the workplace?

**WHAT TO LOOK FOR
IN THE RESPONSES**

Evaluate how the candidate discusses the team, team dynamics and not just themselves

Does the candidate provide examples of how they went above and beyond to help others on the team?

Do they seem passionate about what they are telling you about their role on the team or do you get a sense that they are more comfortable in an individual contributor role?

Do they have a willingness to accept different working styles of other team members?

Are they willing to try new things and challenge conventional thinking even if there are some risks associated with this?

Do they demonstrate ability to incorporate learnings from past experiences and apply them?

Do they demonstrate maturity in describing potential workplace conflicts?

**BEHAVIORAL
INTERVIEW QUESTIONS**

**WHAT TO LOOK FOR
IN THE RESPONSES**

What is your ideal work schedule?
Or what expectations / limitations do you have about the work schedule and potential physical demands (e.g., being on your feet /on the computer for long periods)?

Have you ever been in a situation where you had to take on new tasks or roles? How did you feel about that situation?

Explain the general roles and responsibilities of the CRC role. Ask them how they feel about the demands of the job and what concerns they have about the role, job schedule, etc.?

Do you prefer to work on a single task through to completion, or work on several different projects at the same time?

A person on your team decides to quit. How would you handle that?

Tell me about a time you chose to make a change in the workplace?

Tell me what you have done to introduce change or re-define the way work gets done in your last / prior position.

Tell me how you prefer to take direction or provide input

Explain how you check your work for accuracy, consistency or completeness

Do you get a sense that they can easily adapt to new or different situations with ease or stress?

How they handle or adjust to changes that they have little control over?

Do they receive change as a challenge or opportunity?

Do you get a sense of how they adjust to the ever-changing work environment of a coordinator and having to do multiple things at once with constant interruption?

Are they receptive to and/or proactively seek out ways to use new tools or improve job roles to be more efficient?

Do they come across as willing to receive feedback, confident or willing to contribute new ideas or interact with team members or more reluctant, passive or close-minded?

Do their expectations for the role / work schedule align with what is realistic?

Indicators that they are detail oriented or pay attention to detail

**BEHAVIORAL
INTERVIEW QUESTIONS**

**WHAT TO LOOK FOR
IN THE RESPONSES**

Tell me what you know about clinical research and why it interests you?

Describe a situation where you took initiative without waiting for direction. What was the outcome?

Did they take initiative to learn about clinical research, the role and/or the organization in advance (even if they don't have detailed familiarity with these topics)

Do they demonstrate a willingness to take initiative or take on additional responsibilities and/or work autonomously?

Look for indicators about the level of structure or rule following that they are comfortable with

How does the candidate balance rule following with independent thinking and willingness / ability to challenge conventions in a meaningful and appropriate way?

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**BEHAVIORAL
INTERVIEW QUESTIONS**

Provide the candidate with the full job description and expectations for the role. Ask them how they would approach mastering the competencies and requirements of the job

Alternatively, tell me how you will seek opportunities to exceed the minimum expectations of the entry level role?

Describe for me your ideal company?

Explain the phrase “work ethic” and describe yours

Describe a situation where you made a mistake and what you learned from the experience

What are your expectations for growth, promotion and advancement?

What are your short term (next 2-4 years) and long term goals (5 years or longer)?

How do you deal with diversity in the workplace?

**WHAT TO LOOK FOR
IN THE RESPONSES**

What are their expectations for self-study vs. mentoring?

Do they have a curiosity and learning mind-set or are they more passive in expecting everything to be taught to them?

Do they demonstrate maturity in terms of willingness to acknowledge mistakes and do they demonstrate a willingness and ability to learn and apply lessons learned vs. a more fixed mind set?

Does the candidate have realistic expectations for how they will learn, grow and advance in the role?

Does the candidate’s goals align with what you have to offer in terms of the role, growth and advancement?

Does the candidate appear to be a good cultural fit?

**BEHAVIORAL
INTERVIEW QUESTIONS**

**WHAT TO LOOK FOR
IN THE RESPONSES**

<p>Tell me about the last time you did something for the first time</p> <p>Tell me something you can teach me</p>	<p>Do they light up with enthusiasm when describing the situation, how do they demonstrate zeal or excitement (e.g., taking faster) about something they are interested in and passionate about?</p> <p>How recent was the experience and do they demonstrate a sense of continuous learning and exploration</p>
<p>Walk me through your resume and prior experience</p>	<p>Look for the ability to provide a concise self-story</p>
<p>Tell me about your computer skills. What programs/applications have you worked with and for how long?</p>	<p>Assess comfort level with various technologies and willingness to learn; assess gaps and potential discomforts or limitations in working with new or numerous technologies</p>
<p>Describe a time when you anticipated a problem and took measures to prevent it</p> <p>Describe a scenario where you had to solve a problem and how you approached it</p> <p>Tell me about a time where you lacked the skills or knowledge to complete an assignment</p>	<p>Aim to get a sense of how the candidate analyzes information and makes decisions</p> <p>How resourceful or creative is the individual in solving problems and/or seeking help and support from others?</p>

**BEHAVIORAL
INTERVIEW QUESTIONS**

**WHAT TO LOOK FOR
IN THE RESPONSES**

<p>Describe a situation where you had to communicate something to upper management or positions in authority</p> <p>Tell us about a time when you had a difficult conversation with an authority figure and what you learned from the experience</p>	<p>Assess the confidence and ability to clearly communicate with management and or handle situations that could be more uncomfortable in nature</p>
<p>Describe a time when you had to deal with someone being difficult. How did they handle it?</p> <p>How do you deal with children?</p> <p>What are your values? Your core guiding principles?</p>	<p>Do you get a sense that the candidate is empathetic or has the ability to be empathetic?</p>
<p>What questions do you have for us about this job?</p> <p>Why do you want this job? What is attracting you to this job?</p> <p>How do you see clinical research fitting into the healthcare industry?</p>	<p>Evaluate the number, nature, depth, detail and insights they have about, themselves, the role, the organization and the wider clinical research context</p>

Besides the interview, what are other ways that we can objectively measure or assess some of the entry level competencies?

- General preparedness

Did they come prepared with copies of their CVs (even if previously submitted)?

Have they researched your organization or anything about clinical research?

- Provide the candidate with a medical terminology quiz

- Conduct some simulations or practical hands-on activities including:

Giving the candidate an “in box” or organizational activity with 5-10 tasks to be accomplished for the day and assess how they prioritize the work

Give the candidate a simple informed consent form (1-2 pages), explain the process for informed consent, give them some time to prepare and have them consent you to the sample study. Alternatively, have them explain the purpose and objectives of the study and how well they understand, retain and relate to the information in the consent form.

Ask them to write down instructions on how to make a peanut butter and jelly sandwich (evaluate their handwriting and actual instructions for legibility, organization and clarity)

Have them write a brief essay about a subject they are interested in (about 1 page) or provide them with 3 open-ended questions to respond to on paper or on the computer. Assess their handwriting (if doing this as a paper exercise), grammar, coherency, spelling, etc.

Ask them to pick up a trail of sample email correspondence relating to a given topic (e.g., correspondence from a sponsor on some outstanding queries). Ask them to formulate a response and evaluate the content, tone and accuracy of their communication.

Implement a variety of “pre-tests” to assess core skills, attention to detail such as Criteria Basics Skills Test (CBST) or Computer skills or literacy tests.

Are there other approaches we might consider?

- “Try and Buy” hiring strategies (through temp agencies or shorter-term contracts) may also be helpful which allows both sides an opportunity for an easier “out” if the job isn’t a good fit for the candidate or organization
- Develop an internship or volunteer program for other roles (e.g., data manager, regulatory coordinator) and assess the intern as they perform in these roles to determine if they may be good candidates for the CRC role

What should we look for after the interview?

- Does the candidate provide a thank you note (at all) and in a timely manner? Do they acknowledge the time of the interviewers and express appreciation for the opportunity?

Acknowledgements

ACRP extends sincere appreciation to the volunteers from the following organizations, as well as our team of independent consultants, who contributed their ideas and expertise to the development of these guidelines, including:

Affinity Clinical Research Institute
Amici Clinical Research
Avera Health
Baptist MDA Cancer Center
Cystic Fibrosis Foundation
Driscoll Children’s Hospital
Duke University Medical Center
Edwards Life Sciences
Houston Methodist Research Institute
Infusion Associates
LMC Manna Research
Lyndhurst Gynecologic Associates
Medical College of Wisconsin
Memorial Healthcare System
Nationwide Children’s Hospital - Columbus, OH
Ochsner Baptist
OSF Healthcare
Rady Children’s Hospital – San Diego, CA
Road Runner Research
Spectrum Health
St. Luke’s Hospital – Kansas City, MO
Syneos™ Health
Unified Womens’ Clinical Research
Unity Point Health
University of California-Irvine
University of Nebraska Medical Center
University of Wisconsin-Madison
Vanderbilt University Medical Center

ACRP thanks members of the Workforce Innovation Steering Committee, including:

Amgen	National Institutes of Health
Biogen	National Cancer Institute
Children’s Mercy – Kansas City	NYU Langone Health
Duke Office of Clinical Research	People-Centered Research Foundation
Fomat Medical Research	Pfizer
Greater Gift	PMG Research
IQVIA	PPD
Javara Research	Premier Research
Lurie Children’s Hospital of Chicago	Roche/Genentech
Medical Center of the Americas Foundation	U.S. Department of Veterans Affairs
Medix	Victorian Comprehensive Cancer Centre
Medtronic	
National Institute for Health Research	

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