



## **JOB DESCRIPTION**

**TITLE:** Clinical Research Coordinator  
**DEPARTMENT:** Clinical Trials  
**REPORTS TO:** Clinical Trials Quality & Compliance Coordinator  
**FLSA:** Non-Exempt

### **SUMMARY OF JOB:**

Coordinates the implementation, quality control, and completion of research studies while assisting the Principal Investigator in determining and accomplishing study objectives. Oversees research studies in an administrative and operational capacity while maintaining compliance with guidelines set by policies, oversight and/or governing agencies. Promotes a collaborative, interdisciplinary approach towards patients, families, and all members of the care delivery team in regard to internal and external research projects.

### **RESPONSIBILITIES:**

Colorado West Healthcare System expects job performance to be consistent with its mission and believes that each Employee contributes to improve performance by continuously searching for ways to increase efficiencies and enhance fiscal performance and viability.

### **ESSENTIAL DUTIES AND RESPONSIBILITIES:**

(The following statements are illustrative of the essential functions of the job and do not include other non-essential or marginal duties that may be required. Community Hospital reserves the right to modify or change the duties or essential functions of this job at any time. All responsibilities may not be performed by all incumbents.)

#### **Under the direction, supervision and/or coordination of the Principal Investigator, the Clinical Research Coordinator:**

1. Utilizes knowledge of study protocol, medications, procedures, infection control, safety precaution to initiate appropriate interventions by assisting, coordinating, performing, and/or overseeing all clinical related aspects of assigned research protocols and research subjects.
2. Coordinates and performs responsibilities related to research participants, including determining subject population availability, developing informed consents and screening materials, screening and recruiting subjects, coordinating referrals for external clinical trials, and/or coordinating with referring physicians to provide information regarding available research projects to maintain good communication and a strong referral basis.
3. Is responsible for overseeing and/or scheduling subject visits, ensure that informed consent(s) have been obtained and are adhered to, answers subject inquiries, oversees study visits, and acts as a liaison between participants and study-related parties.
4. Recognizes, tracks, and reports adverse events and protocol deviations as required by study protocol or other regulations.

5. Ensures that all research related documentation is done timely and meets requirements by being Attributable, Legible, Contemporaneous, Original, Accurate and Complete. (ALCOA-C)
6. Collaborates with members of the health care team that provide direct patient care to research subjects to provide protocol related guidance to ensure quality patient care that is protocol compliant.
7. Develops and maintains patient databases, investigational logs, records of drugs administered, medical devices monitored, and/or procedures followed.
8. Initiates patient care meetings with the health care team as needed to revise the plan of care as the patient's condition and study protocol warrant.
9. Coordinates with clinical staff to obtain study-related biospecimens, and participates in sample processing and shipment. IATA training required.
10. Represents the research program at meetings, national and international research consortia.
11. Prepares reports for organizations and agencies regarding research progress and outcomes.
12. Keeps current on advances in research conduct and regulations by participating in educational programs.
13. Monitors enrollment goals and initiates strategies to promote enrollment and participant compliance.

**Other research-related duties may include, but are not limited to:**

1. Assist with study budgets, coverage analysis and sponsor billing.
2. Assist with timely and accurate data submission and query resolution.
3. Help prepare for / schedule site visits made by sponsors or federal agencies during the course of and at the close of a research study.
4. Assist with preparation, submission and maintenance of IRB, FDA, NCI, NIH, NSF and/or other regulatory documents and research correspondence.
5. Assist in the development of policies, procedures, and process improvements for departmental implementation throughout the course of various research projects.
6. Participates in quality management to positively affect patient and system outcomes in an effort to improve the patient's research experience.
7. Contributes to developing educational materials for the purposes of educating staff and the community regarding general research information, research studies, and related research issues.
8. Supervises, mentors and/or trains new or junior research staff.
9. Other duties as assigned.

**QUALIFICATIONS:**

To perform this job successfully, an individual must be able to perform each essential duty satisfactorily. The requirements listed below are representative of the knowledge, skill, and/or ability required. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential functions.

**EDUCATION and/or EXPERIENCE:**

Associate or Bachelor's degree in business, science or related field. With at least (1) year of Oncology Experience (Preferred). With at least (1) one year of Research Experience (Preferred). Knowledge of Good Clinical Practices, FDA, HIPAA and IRB regulations, having at least a basic understanding of research procedures.

OR

Equivalent Experience and/or Education

**CERTIFICATES / LICENSES:**

- ACRP / SOCRA certification within 6 months of being eligible (SOCRA is preferred);
- CITI and IATA within 30 days of being hired.

**LANGUAGE SKILLS:**

Must be able to speak, read and write English. Ability to read and interpret documents such as physician orders, medical charts, safety rules, operating and maintenance instructions, and procedure manuals. Ability to write routine reports and correspondence. Ability to effectively present information in one-on-one and small group situations to supervisors, patients, patient's family and other employees of organization. Able to work in a team-oriented environment.

**MATHEMATICAL SKILLS:**

Ability to add, subtract, multiply, and divide in all units of measure, using whole numbers, common fractions, and decimals. Ability to compute rate, ratio, and percent.

**REASONING ABILITY:**

Ability to solve practical problems and deal with a variety of concrete variables in situations where only limited standardization exists. Ability to interpret a variety of instructions furnished in written, oral, diagram, or schedule form.

**INTERPERSONAL SKILLS:**

Demonstrates exceptional customer service skills using the "Whatever It Takes" philosophy; builds relationships and proactively respects others. Requires adaptability with regular interpersonal contact.

**DECISION MAKING ABILITY:**

Work limited by standards and procedures. Adapts to recurring operational situations using formal and informal channels. Unusual situations are reviewed with a manager.

**ANALYTICAL ABILITY:**

Apply basic business or technical principles to routine and moderately complex problems. Concentrates and pays close attention to detail.

**COMPUTER SKILLS:**

To perform this job successfully, an individual should be computer-literate and have working knowledge of Microsoft Office applications.

**PHYSICAL DEMANDS:**

The physical demands described here are representative of those that must be met by an employee to successfully perform the essential functions of this job. Reasonable accommodations may be made to

enable individuals with disabilities to perform the essential functions.

While performing the duties of this job, the employee is regularly required to sit; have manual dexterity; handle or feel; talk and hear. The employee is occasionally required to stand; walk; reach with hands and arms; climb or balance; and stoop, kneel, crouch, or crawl. The employee must regularly lift and/or move up to 20 pounds. Specific vision abilities required by this job include close vision, distance vision, color vision, peripheral vision, depth perception, and ability to adjust focus.

**WORK ENVIRONMENT:**

The work environment characteristics described here are representative of those an employee encounters while performing the essential functions of this job. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential functions.

While performing the duties of this job, the employee is occasionally exposed to moving mechanical parts, risk of electrical shock, exposure to infectious diseases, and transmission of airborne disease. The noise level in the work environment is usually moderate.

**GENERAL COMPLIANCE REQUIREMENTS FOR ALL EMPLOYEES:**

- Attends annual compliance and privacy training.
- Responsible for complying with all federal, state and local rules and regulations.
- Must comply with the Code of Conduct Guide.
- Reports any observation of fraud, waste, abuse, and/or privacy violations to HR or CCO.
- Reports any conflict of interest or relationship immediately.

**HIPAA:**

Ensures and adheres to strict confidentiality when handling patient information, according to the HIPAA Privacy Act and hospital policy and procedure regarding confidentiality. Complies with all hospital information security practices.

Has knowledge of and adheres to all compliance regulations, policies and procedures.

**Final Section** I understand that my employment is for an indefinite period of time and that his facility can change wages, benefits, and conditions of employment at any time.

\_\_\_\_\_  
Employee Name & Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Supervisor Name & Signature

\_\_\_\_\_  
Date