

# **Clinical Research Coordinator Job Description**

The Clinical Research Coordinator (CRC) is a specialized research professional working with and under the direction of a Principal Investigator (PI) on multiple ongoing dermatology research studies,

predominately phase II to IV clinical trials. While the PI is ultimately responsible for the clinical trial, the CRC is responsible for the facilitation and coordination of the daily clinical trial activities and plays the central, critical role in the conduct of the study. The CRC works collaboratively with the entire OMRC team, pharmaceutical sponsors, and site monitors to ensure productivity and timely completion of studies. Based on interest and background, the CRC may also provide support as a back-up laboratory technician.

### **Essential Functions:**

Utilizing Good Clinical Practice (GCP), the CRC ensures assigned studies are conducted in accordance with the guidelines of the Food and Drug Administration (FDA) and Office for Human Research Protections (OHRP).

### **Clinical Research Functions:**

- Ensures site compliance with research protocols by reviewing all regulatory requirements to confirm implementation of appropriate methods, practices, and procedures for all research activities
- Works with the PI to manage the day-to-day activities of the study including problem solving, communication and protocol management
- Develops accurate source materials and ensures compliance from site staff
- Provides accurate and timely data collection, documentation, entry, and reporting in both sponsor and OMRC databases
- Ensures appropriate credentialing and training of the entire OMRC team
- Supports the regulatory staff in the maintenance of regulatory documents in accordance with OMRC standard operating procedure and applicable regulations
- Interfaces with research patients including supporting efforts of the clinical staff to determine eligibility, obtain informed consent, collect vitals signs and other data, photographs, disbursing investigational drug, administrating and teaching patient administration according to protocol
- Communicates and collaborates specific study requirements to the research team, including internal and external parties, sponsor, monitors, PI, and study participants
- Ensures compliance with research protocols, by providing ongoing quality control audits, including maintaining ongoing investigational drug accountability

### **Back-Up Laboratory Functions (in appropriate candidate):**

- Ensures the accurate collection of acceptable specimens, including venipuncture, and follows all processing and International Air Transportation Association (IATA) shipping requirements associated with each individual sample
- Maintains accurate and complete documentation of patient information, equipment, and test results to comply with regulations and study protocols
- Ensures scheduled tests have been completed, as per protocol
- Maintains laboratory supply inventory for each study by checking stock to determine inventory level;
  anticipating needed supplies; placing and expediting orders for supplies; verifying receipt of supplies
- Assembles accurate subject visit supplies, following protocol driven standards

## Other:

Maintains knowledge of and employs OMRC Standard Operating Procedures

- Participates w/ PI and study team to identify and prioritize the development of systems and infrastructure to maintain research quality and compliance
- Required occasional paid travel to attend out-of-state study training meetings
- No supervisory responsibilities
- Other duties as assigned
- CPR-certification required (can attain through OMRC)

### **Qualifications:**

- Candidates with a bachelor's degree in a scientific, health-related or business administration program preferred. At minimum, a candidate must have a bachelor's degree
- Preferred candidates will have at least one full year of experience coordinating in a clinical research environment
- Those interested in back-up laboratory position will have at least one full year of phlebotomy experience
- Detail oriented and meticulous in all aspects of work; flexible, organized, and tenacious
- Ability to work well independently, as well as in team environment
- Strong follow-through skills and ability to proactively identify and solve problems; demonstrated initiative is imperative
- Must have professional demeanor, strong communication skills with the public as well as physicians/researchers
- Strong interpersonal, customer service and multi-tasking skills are critical
- Must be proficient in Microsoft Office, Word and Excel, electronic health systems and databases used in research environment, or have a willingness to learn and demonstrate proficiency within six months of hire
- Possess the ability to work well under pressure, multi-task and manage deadlines
- Knowledge of GCP, federal, state, and local regulations, including HIPAA policies and procedures, preferred
- Knowledge of medical terminology, clinical medicine, clinical trials, and GCP concepts preferred
- Ability to pass and receive IATA certification, for laboratory role, if interested

### **Physical Requirements**

- Physical Requirement Feeling (sensing textures and temperatures) (Frequently)
- Physical Requirement Fine Motor Skills (pinching, gripping, etc.) (Frequently)
- Physical Requirement Hearing (Frequently)
- Physical Requirement Pushing/pulling (Occasionally)
- Physical Requirement Reaching (Occasionally)
- Physical Requirement Sitting (Frequently)
- Physical Requirement Standing (Frequently)
- Physical Requirement Stooping/crouching/kneeling/crawling (Occasionally)
- Physical Requirement Talking (Frequently)
- Physical Requirement Tasting/smelling (Occasionally)
- Physical Requirement Walking (Frequently)
- Physical Requirement Near Vision (Constantly)
- Physical Requirement Color Discrimination (Occasionally)
- Physical Requirement Use of keyboard, mouse and/or computer equipment (Constantly)
- Physical Requirement Lift up to 35 pounds without assistance (Occasionally)
- Occupational Exposure/Risk Potential Inside office environment (Applicable)
- Occupational Exposure/Risk Potential Airborne communicable diseases (Applicable)

- Occupational Exposure/Risk Potential Blood-borne pathogens or bodily fluid (Applicable)
- Occupational Exposure/Risk Potential Fumes or airborne particles (Applicable)

Full-time position – 40 hours. Work days: Monday through Thursday, Hours: 7:00 am – 5:00 pm. Salary commensurate with experience.

Oregon Medical Research Center is an equal-opportunity employer. Applicants needing accommodation to apply should contact Molly Blauvelt at mblauvelt@oregonmedicalresearch.com