



## Clinical Research Assistant (CRA) | Clinical Trial Assistant (CTA)

Department	Consumer Research
Basic qualification required	B.S.
Location	Winnipeg
Experience	1-2 Years
Brief JD	<p><b>Responsible to:</b></p> <p>Associate Director, Clinical Operations with a dotted line to Clinical Research Coordinators (North America)</p> <p>Team Lead (India)</p> <p><b>Job Description / Roles and Responsibilities for Job Title:</b></p> <p>The primary responsibility of the Clinical Research Assistant   Clinical Trial Assistant is to perform basic assigned study tasks, to interact with study participants, and assist the Clinical Research Coordinator in completing various tasks.</p> <p><b>Records Data</b></p> <ul style="list-style-type: none"><li>• Accurately and properly handles study data Follows supervisor's directions as indicated by the SOP in the recording of data</li><li>• Locates appropriate paperwork efficiently</li><li>• Consistently writes in a legible manner</li></ul> <p><b>Organizes and updates binder as needed</b></p> <ul style="list-style-type: none"><li>• Demonstrates ability to efficiently and effectively organize material following the Cliantha binder format</li><li>• Updates appropriate binder data/information on a daily basis</li></ul> <p><b>Interviews panelists, as applicable</b></p> <ul style="list-style-type: none"><li>• Greets and welcomes study participants to Cliantha</li><li>• Verifies accuracy of information the study participant gave to the recruiting office during the screening process</li></ul>



- Demonstrates ability to put study participant(s) at ease, even when asking delicate or sensitive questions
- Uses simple language to explain steps of specific test protocol and confirms the panelist's understanding
- Provides study participants with directions to appropriate testing site
- Exhibits ability to synthesize study participants' information and ask pertinent follow up questions
- Schedules required study participant(s) follow up visits and explains the importance of continued participation
- Obtains IRB | IEC approved informed consent (ICF), medical histories, and demographic information from potential volunteers

#### **Completes various study procedures**

- Performs necessary procedures required per protocol to accomplish the screening visit such as but not limited to ECGs and Vital Signs
- Answers questions, reviews protocol, and works closely with the screening coordinator, recruitment and regulatory department.
- Asks for clarification and assistance as needed
- Study related tasks (such as Meals distribution, Recording, Visual Acuity, Installation, Assembly, Check In procedures, baggage search, or as needed.)
- Handling of Bio Instruments available at Consumer Research
- Complete documentation part regarding instrument handling and other study related forms.
- Preparation of sample collection labels/vacutainers under direction of clinical research coordinator or manager
- Completes all study related activities following the sites SOPs, policies, and protocol in order to meet the study timelines
- Protects sponsor confidentiality by limiting



discussion of ongoing protocols with monitors and other industry representative

- Communicates status of task(s) to be completed to supervisor
- Shows pride in work by completing all tasks in a neat and accurate manner

**Performs simple data entry**

- Utilizes data program software or Cliantha provided sheets, accurately entering and editing simple data

**May be responsible for Sample Log-ins and Returns**

- Accurately and according to SOPs, identifies, weighs and legibly records each sample item against protocol requirements
- Stores samples neatly and efficiently in appropriate place, as defined by study protocol or directed by supervisor
- Verifies accuracy of package content against invoices
- Packages test samples properly and promptly, and returns samples to designated source, as specified by the protocol

**May conduct 'on-the-job' training with the associate**

- Explains step-by-step procedure using clear and simple language
- Uses proper technique in demonstrating step-by-step procedure dictated by SOP
- Observes associate practicing procedure and provides corrective feedback
- Utilizes appropriate job aids to assist in training
- Records and documents training for associate's training binder
- Provide administrative support as required, including but not limited to copying, numbering, binding and archival of project and supporting documentation



### **May calibrate equipment**

- Conducts accurate calibration of equipment as detailed in SOPs
- Immediately reports equipment problem/malfunction to appropriate associate
- Under close supervision, may be responsible for sample(s) preparation
- Demonstrates the ability to accurately prepare samples following supervisor's explicit calculations/instructions
- Demonstrates ability to properly use lab equipment in accordance with the SOPs to accurately fulfill requirements of the study protocol
- General administration (cleanliness, housekeeping, laundry, equipment) of the consumer facility.
- Coordination with clinical research Coordinator, Sub Investigator, and Principal Investigator regarding study requirements.
- Works with others in a cooperative manner
- Participate in training sessions and protocol implementation
- Execute other duties that may be required by other members of the management team as training and experience allows

### **WORKING CONDITIONS AND 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 necessary and can be made, to enable individuals with disabilities to perform the essential functions. The noise level in the work environment is usually moderate and dealing with groups of people is needed in this role. Primarily office setting. Work hours



may vary according to the needs of the clinic and specific studies. Evening, weekend or holiday hours may be required

### **QUALIFICATIONS & EDUCATION**

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.

#### **QUALIFICATION:**

To perform this job successfully, an individual must be able to perform each essential duty satisfactorily. Graduation for high school, GED or demonstrated equivalent with previous medical knowledge.

#### **Skills and Abilities:**

- Ability to follow directions and complete assignments
- Knowledge of proper English grammar
- Knowledge of basic computer skills (keyboarding, data entry)
- Ability to write neatly and legibly
- Ability to work with others in a cooperative manner
- Demonstrated knowledge of Cliantha Research policies, regulatory requirements and quality standards (e.g. GCP, ICH GCP)
- Ability to communicate effectively in verbal or written form
- Ability to react calmly and effectively in emergency situations
- Maintain high level of organization, efficiency and accuracy
- Ability to work independently or as a contributing team member



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|  | <ul style="list-style-type: none"><li>• Ability to manage multiple priorities and flexible schedule</li><li>• Ability to identify and solve problems effectively and efficient</li></ul> |
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Interested candidates can send their resume at [kstowe@cliantha.com](mailto:kstowe@cliantha.com)