CLINICAL TRIALS OF TEXAS, INC.

Job Description

Job Title: Clinical Research Coordinator I

Department: Clinical **Wages: Salary / Classification:** Exempt

I. PURPOSE: To coordinate activities and perform duties and procedures related to the start-up, conduct and close-out phases of clinical pharmaceutical and device research protocols. To obtain clean, objective and accurate data within sponsor timelines while following applicable CTT SOPs, policies and procedures, federal regulations, medical ethics, Good Clinical Practices (GCPs), International Council of Harmonization (ICH), Institutional Review Board (IRB) requirements, and in compliance with specific sponsor protocol requirements. All responsibilities should be completed in accordance with CTT's Mission Statement and Employee Manual.

II. JOB RELATIONSHIPS:

Reports to: Team Lead
Sr. VP, Operations

Workers Supervised: None

Interrelationships: Works closely with CTT staff, patients and sponsor/contract research organization (CRO) representatives. Works frequently and to varying degrees with physicians and nursing staff at offices separate from CTT. May, from time to time, work with hospital staff members.

III. RESPONSIBILITIES:

A. Represent CTT in a professional and courteous manner (verbal, written and in appearance) when interacting with CTT staff, sponsors, IRBs, patients/subjects, nursing and medical staff members of various clinics, hospitals and physician's offices;
B. Read, understand and is able to accomplish protocol specified patient visits and procedures;
C. Clearly and concisely document patient assessments, observations, test results and other study related information per federal regulations, protocol requirements and GCPs;
D. Obtain patient informed consent according to federal regulations, GCPs and IRB requirements;
E. Is creative and diligent in recruiting qualified study subjects into assigned protocols to fulfill enrollment obligations within the sponsor's timeline while following regulations and rules governing medical ethics, IRB, GCP and ICH guidelines;
F. Complete all required training in a timely manner;
G. Schedule and conduct patient visits according to protocol requirements and timelines;
H. Maintain accurate and complete written source documentation of patient visits and protocol related activities;
I. Accurately complete case report forms (CRFs &/or eCRFs) and/or worksheets generated by the sponsor;
J. Maintain confidentiality of patient and protocol issues as appropriate and as bound by Confidentiality Agreements with CTT, between CTT and sponsors, and between CTT and other entities, as well as HIPAA regulations;
K. Promptly report adverse events to supervisor and/or Principal Investigator/Sub-Investigator as deemed necessary;
L. Report Serious Adverse Events (SAEs) to sponsor within 24 hours of becoming aware of the SAE. Also report the SAE to supervisor, Principal Investigator and/or Sub-Investigator;
M. Account for clinical trial materials (i.e. CRFs, study drug, lab supplies, and/or other required items) and ensure availability of appropriate amounts for the conduct of the study;
N. Maintain ongoing communication with President, Principal Investigator, Sub-Investigators, and other persons assisting with the trial and documents these communications according to protocol requirements and CTT policies;

O. Attend required training courses/conferences in order to stay abreast of current and changing federal regulations and CTT policies;
P. Pursue educational opportunities to increase knowledge of the research process and associated rules and regulations governing clinical research;
Q. Attend Investigator Meetings and/or other trainings as directed;
R. Perform all study-related duties in a time- and cost-effective manner in adherence with CTT policies;
S. Perform all duties in a safe and prudent manner;
T. Perform other duties as assigned.

IV. PHYSICAL REQUIREMENTS AND/OR ENVIRONMENTAL FACTORS:

1. Work is normally performed in a typical interior/office work environment;
2. Travel required;
3. Exposure to human bodily fluids;
4. Laboratory processing procedures;
5. Subject/Patient care;
6. Daily computer use;
7. Occasional night and weekend work schedules;
8. Ability to properly lift up to 35 pounds and occasionally more than 35 pounds;
9. Ability to drive, and daily availability of an automobile.

V. MINIMUM REQUIREMENTS:

Education: Bachelor's degree or adequate experience within the field of research to compensate.

Experience:

1. Minimum of one year experience within the field of clinical or biological research.

Knowledge and Skills:

1. Ability to read, understand and assimilate protocol specified requirements and/or to ask appropriate questions as needed to gain knowledge and understanding;
2. Must possess a basic knowledge of research design, patient care practices, GCPs, FDA regulations and a thorough knowledge of medical terminology;
3. Possesses excellent interpersonal skills including written and oral communications;
4. Is moral and ethical in decision-making and during interaction with patients, sponsor and IRB representatives, physicians and staff at satellite clinics, and other employees. ECG, phlebotomy skills, and any other technical skills related to the completion of a study visit as required by the protocol.

AGREED TO:

_____ _____
Employee Date

_____
Employee Printed Name

_____ _____
Team Lead CRC Date

_____ _____
President/CEO Date

cc: Employee