CLINICAL TRIALS OF TEXAS, INC.

Job Description

Job Title: QC Data Coordinator I

Department: QC Department

Salary: Hourly
FLSA Classification: Non-Exempt

I. PURPOSE: Provide quality control and data entry for charts that are entered into the QC data entry process. Work with clinical research coordinators to ensure CTT standards are utilized and data entry is provided to the sponsors in an accurate and timely manner.

II. JOB RELATIONSHIPS:

Reports to: QC Data Manager
Sr. VP, Operations

Workers Supervised: None

Interrelationships: Works closely with clinical research study coordinators and other staff and sponsors/contract research organizations (CROs).

III. RESPONSIBILITIES:

The QC Data Coordinator I is responsible for, but not limited to the following job duties:

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. Conduct a thorough and precise review of study charts utilizing CTT SOPs and sponsor protocols. Indicate data points that are missing or discrepant and identify and report any trends to the QA/QC Manager;
C. Accurately enter data into an eCRF/CRF system according to the sponsor provided eCRF/CRF guidelines in a timely manner;
D. Identify and report missing data points or inconsistencies to the clinical research coordinator and QA/QC Manager as soon as possible;
E. Source document creation;
F. Attend SIV meetings;
G. Report any discrepancies between the source and CRF/eCRF immediately to the CRC and the QA/QC Manager;
H. Resolve open queries thoroughly, accurately and in a timely manner;
I. Assist in sponsor monitor visits to resolve queries in a timely manner;
J. Possess the ability to work closely with other staff members and sponsor representatives in a professional manner;
K. Perform all duties in a time- and cost-effective manner;
L. Perform other tasks as required.

IV. PHYSICAL REQUIREMENTS AND/OR ENVIRONMENTAL FACTORS:

A. Work is normally performed in a typical interior/office work environment;
B. Local travel required;
C. Monitor/Sponsor Customer Service;
D. Daily computer use;
E. Occasional night and weekend work schedules;
F. Ability to properly lift up to 25 pounds and occasionally more than 25 pounds;
G. Ability to drive, and daily availability of an automobile.

V. MINIMUM REQUIREMENTS:

Education: Bachelor's degree or equivalent experience.

Experience:

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

Knowledge and Skills:

1. Must have the ability to understand medical terminology and research concepts;
2. Must have ability to identify appropriate subject care, relate in a professional and knowledgeable manner to physicians, pharmaceutical sponsors/CROs, and IRBs;
3. Must have a basic knowledge of Good Clinical Practice (GCP), CTT SOPs, computers, the internet, and Microsoft Office applications.

Special Requirements:

1. Manage multiple tasks, ability to prioritize, meet deadlines, work independently, exercise initiative and demonstrate sound judgment, consistently demonstrate effective oral and written communication.

AGREED TO:

_____ _____
Employee Date

_____
Employee Printed Name

_____ _____
QC Data Manager Date

cc: Employee