Sansum Diabetes Research Institute

Job Title: Volunteer Clinical Research Assistant
Department: Clinical Research / Diabetes Innovation
Reports to: Principal Investigator
FLSA Status: Volunteer
Contact: Gal Haroush, Clinical Research Coordinator, 805.682.7640 ext 263

ESSENTIAL DUTIES AND RESPONSIBILITIES

In close collaboration with the Clinical Research Coordinator and the principal investigator, the incumbent will serve as a support staff to the clinical research department in clinical trials, following company SOPs. ICH GCPs, protocols, all regulator laws, including but not limited to FDA – Code of Federal Regulations and state laws. Duties may include, but not limited to: conducting informed consent, data entry, assisting with study visits, study recruitment, maintaining Regulatory binders, and performing specific study related duties, per protocol. Some weekends and evening hours may be required. This position will be responsible for the following specific functions:

1. General Clinical tasks including: measuring vital signs such as pulse, point of care A1c, temperature, blood pressure, weight, height, and waist circumference, collecting and processing lab specimens, preparing treatment rooms, assisting with the Regulatory Binder.
2. General Office tasks including answering the phones, scheduling subject appointments, contacting subjects to verify appointments and describe studies, data entry into Clinical Trial Management System (CTMS), other daily tasks as assigned by the clinical coordinator such as study start up and study close out duties.
3. Work closely with the Clinical Coordinator and the PI to become thoroughly familiar with and the ability to assist with the execution of the clinical trial, per protocol. This includes completing source documents, completing case report forms (CRFs), developing and administering informed consent forms, creating source documents from the protocol and CRFs, verify subject diaries (when applicable) for the research studies, following study subject from the beginning of the trial until the end of the trial or until the subject withdraws informed consent.
4. Obtain certification in the following: Good Clinical Practices - NIH, Protecting Human Subjects – NIH, Human Subjects Protection – Cottage IRB, and IATA – Mayo Clinic, and all certified trainings required by the sponsor.
5. Complete all training on the research assistant checklist in a timely manner and turn into clinical coordinator.
6. Assist in maintaining the clinical trial subject database.
7. Generate reports for clinical coordinator on patient recruitment efforts and enrollment.
8. Maintain accountability of professional growth development.
9. Perform necessary functions as described by the Primary Investigator and clinical coordinator for the conduct of the clinical protocol, including but not limited to, assisting with oversight of bench staff operations of study specific duties, assisting the clinical coordinator with study visits and reporting AEs to the sponsor.
10. Maintain strict confidentiality of patients, employees and company information at all times and adhere to HIPAA guidelines.
11. Recruit subjects for trials and create a recruitment plan for each specific study.
12. Develop credible relationships with subjects and both internal and external customers.
13. Follow established policies, procedures, and objectives, quality improvement objectives, and safety, environmental, and/or infection control standard.

QUALIFICATIONS:
The incumbent must be able to perform each essential duty satisfactorily. Training will be provided where necessary, and specific assistance in refreshing the incumbent in those areas where appropriate. 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.

Basic know of office practice and office equipment
Basic knowledge of computer systems for word processing, electronic mail, data entry
Basic knowledge of Microsoft office especially Excel
Ability to type
Excellent communication skills both oral and written
Ability to work with multiple staff members and prioritize work
Ability to work under stress
Ability to work independently and with careful attention to detail
Ability to transfer data accurately, in the required format, and in a timely manner
Must be able to establish rapport and communicate with clients of diverse cultural and educational backgrounds
Ability to hand multiple projects of different types

EDUCATION AND EXPERIENCE
Experience working in a medical setting
Scientific education desirable
High school diploma and minimum 2 years of college

LANGUAGE SKILLS
The ability to read and speak English clearly is mandatory. The ability to interpret documents such as safety rules, Standard Operating Procedures, and procedure manuals. The ability to communicate information to coworkers as well as management in a clear and concise manner is essential.

Ability to speak Spanish is desirable but no required.

REASONING ABILITY
The ability to apply common sense understanding to carry out instructions, either written, or, or diagram form. The ability to use critical thinking skills when working under pressure. The ability to deal with problems involving several variables in standardized situation must be a proven ability. The ability
to prioritize tasks and activities in a manner consistent with direction from CRC or PI. Ability to multitask on different projects and prioritize where needed.

PHYSICAL DEMANDS
The incumbent is regularly required to sit, talk and hear. The incumbent frequently is required to use hands to finger, handle or feel equipment, paper, or files. Must be able to operate a computer keyboard as well as see a computer monitor display screen. The incumbent is occasionally required to stand, walk, and reach with hands and arms. The employee must occasionally lift and/or move up to 10-20 pounds. Specific vision ability required by the job include close vision. The employee must be able to stand on their feet for multiple hours, the job may have a shift that requires standing for 4+ hours.

The position requires the manual dexterity and adequate vision to record data onto data sheets, and enter data into a computer’ adequate hearing and verbal communication skills to conduct interviews (in person or on the phone).

WORK ENVIRONMENT
The work environment would be generally described as an office setting with clinical and laboratory facilities adjacent to the primary work area. The ability to move within all three of these areas may be required in the execution of the employee’s functional activities. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential functions. The noise level in the work environment is usually moderate and the illumination of the work area is primarily with fluorescent artificial lighting.

This position is associated with exposure to blood borne pathogens and communicable disease requiring the use of universal precautions at all times.