

Title of Job: *Site Manager*

Description: The Site Manager (SM), as delegated by the principal investigator, executes and coordinates daily clinical research activities according to CRA's SOPs, GCP and FDA/ICH guidelines. Oversees the other coordinators and assistants to ensure a smooth site operation. Ensures IRB approved protocols are implemented and followed. Executes informed consent process and monitors patient status and safety; collects and organizes research data; schedules and conducts study specific training and site in-services to study related staff on new or amended protocols; educates patients and their families about treatments and possible side effects; has general operational responsibilities for the site. The Site Manager must also be able to perform clinical tasks (i.e. phlebotomy, EKGs, vital signs, etc.). SMs typically perform tasks such as:

- Site preparation
- Workload analysis and study assignments
- Obtaining informed consent
- Patient screening and recruitment
- Patient enrollment
- Conducting study visits
- Maintaining and dispensing study product and supplies
- Completing and ensuring the quality of case report forms
- Maintaining source documents
- Ensuring site quality
- Responding to queries in a timely manner.

Educational Qualifications: BA/BS; RN, BSN preferred. More than 2 years experience in study coordination may be substituted.

Experience/Training:

- Phlebotomy and EKG experience;
- Familiarity with GCP and FDA/ICH regulations;
- Microsoft Office skills; and
- Completion of CRA's proficiency exams.

Licenses. etc: Certification from either ACRP (CCRC) or SoCRA (CCRP) is required once all qualifications have been met. HAZMAT certification and NIH training. Maintain RN License (if applicable).

Status and Scope: Reports to the Region Manager or Director and/or VP of Clinical Operations.

FLSA Status: Exempt

Essential Job Duties:

1. Excellent written, oral, interpersonal communication skills, strong organizational talents with attention to detail;

Site Manager

2. Becomes thoroughly familiar with the protocol, case report form, informed consent, source documentation, patient diary (when applicable), and study medication(s) for the assigned research study;
3. Adheres to GCP, ICH, NIH, HIPAA, FDA Regulations and SOPs. Assists the Director of Regulatory in maintaining ongoing regulatory documents;
4. Establishes rapport with sponsor representatives and maintains frequent face-to-face, written and telephone contact with various persons involved in the study, including but not limited to the patients, relatives/friends of the patients, doctors, pharmaceutical sponsors and all levels of the company;
5. Serves as Study Coordinator for a number of clinical trials;
6. Manages onsite research protocol activities and assist staff in organization to ensure study protocol procedures are completed per CRA's SOPs and good clinical practices;
7. Manages and participates in study recruitment to ensure enrollment goals are met or exceeded;
8. Directs and guides Research Assistant on study specific tasks. Assists in training Research Assistants;
9. Facilitates the completion and timely return of questionnaires to the Director of Marketing;
10. Performs basic lab procedures, such as: blood specimen collection, centrifuge operation, storing and shipping of lab specimens, accountability of specimens and notification of courier for specimen pick-up, schedules patients, obtains informed consent, administers study medications;
11. Performs appropriate research protocol procedures which may include, but are not limited to: vital signs, pregnancy tests, blood collection and processing, ECGs, and alcohol breath tests and pain assessments;
12. Ensures study related reports and patient results are reviewed by an investigator in a timely manner;
13. Responsible for completion of case report forms, ensuring accuracy of data and reporting of adverse events to sponsor;
14. Dispenses investigational product and instructs subjects on usage and potential drug interactions;
15. Practical knowledge of document processes and reporting of SAEs, 1572s, CRFs, ICFs, etc.;
16. Ensures that training of investigators and staff are current for all research studies;
17. Provides patient education regarding disease process and involves patient and family in decision-making processes;
18. Generates reports for supervisor on patient enrollment and tracking;
19. Tabulates enrollment statistics and attends the bi-weekly marketing meeting;

20. Maintains accountability of own ongoing professional growth and development;
21. Responsible for guiding site through leadership skills and positive attitude;
22. Performs necessary functions as approved by Clinical Research Advantage, for the conduct of clinical research;
23. Maintains strict confidentiality of patients, employees and company information at all times and adheres to HIPAA Guidelines;
24. Responsible for drug accountability, maintaining logs and inventory of study product and supplies;
25. Coordinates and conducts pre-study, initiation, monitoring and close-out visits with the pharmaceutical representative, including completion of minutes and follow-up reports;
26. Maintains contact and interact with monitors and sponsors;
27. Works under direction of principal investigator;
28. Serves as main daily contact to principal investigator;
29. Attends investigator meetings; and
30. May perform other duties not specifically listed in this job description as assigned by their immediate supervisor.

Leadership Traits

High Standard of Personal Ethics - *Decisions made under pressure and/or temptation separate the great ones from the impostors.*

High Energy - *Great leaders are not exhausted by dealing with petty issues. These people know right from wrong as well as the difference between what's truly important and what's merely interesting.*

The Ability to Work Priorities - *The difference between setting priorities and working them through is the difference between a dreamer and a doer.*

Courage - *The willingness to take risks and accept responsibility for the outcome is a consistent quality among effective leaders. Either you or your fears will control everything you do. An organization will be no bolder than the leader.*

Committed and Dedicated - *Hard working leaders will eventually develop dedicated and hard working organizations regardless of who they start with or the experience they bring to the job.*

Creativity – *Effective leaders are innovators who bore easily and prefer shaping tomorrow to repeating yesterday.*

Goal Orientation to Make Tough Decisions - *Goal orientation produces a drive and energy that shield us from the pain of the task. Keeping an organization focused increases efficiency.*

Inspired Enthusiasm - *Genuine enthusiasm is contagious. People look to their leaders for enthusiasm. The inspiration level of the organization is directly proportionate to the enthusiasm of the leader--be it high or low.*

Level-Headed - *Good leaders respond to problems rather than simply react. A leader who can stay cool under pressure inspires confidence among those in the organization and empowers them to do the same.*

Help Others Succeed – *This is the mark of a truly great leader. Synergy is created when a leader truly invests his or her efforts in the success of others.*