Position/Title: **Internal Clinical Research Associate I**

Job Description

Has responsibilities for Trial Master File (TMF) documentation and associated document control functions. Acts as a project resource and liaison for Hart Clinical Consultant personnel, sponsors and assigned clinical sites, in accordance with Good Clinical Practice (GCP), Good Documentation Practice, federal regulations, international guidelines and applicable SOPs. Provides support on key deliverables and special projects as needed.

1. Ensures timely collection and archiving of required trial documentation, according to protocol, monitoring plan, procedures and regulations.
2. Under supervision, provides quality review of essential study documents being stored/archived in the electronic clinical documents control system (CDCS), for completeness and accuracy, to identify/resolve discrepancies and obtain missing documents or information.
3. Provides reviewed documents to CDCS staff for appropriate filing.
4. Provides periodic verification of correct identification of documents in the CDCS based on naming and filing conventions, and proper placement within the CDCS by the CDCS staff to ensure ability to promptly and accurately retrieve documents when needed.
5. Contacts clinical sites, and other research partners such as outsourced functions (e.g., data management), to obtain documentation or communicate additional requirements such as document corrections or updates.
6. Tracks essential study documents and notifies appropriate personnel when documents are missing, inadequate or about to expire.
7. Tracks monitoring reports and other site records; notifies CRAs and/or Project Leads when Monitoring Visit Reports are overdue.
8. Works closely with Project Management, Field CRAs and CDCS staff regarding study status, document status, current priorities and timelines.
9. Assists, when required, with retrieval of specified documents for internal or site audits or inspections as identified by senior staff management, or Quality.
10. Provides support for the review, approval and processing of standard operating procedures and associated forms/templates per procedure.
11. Maintains HCC internal documentation including guidelines, policies and procedures in designated system.
12. Notifies HCC staff of training needs, provides support in assignment of training and identification training gaps; works with staff to obtain training documentation. Assists with maintenance of the HCC staff Training Matrix.
13. Maintains HCC personnel files, e.g., CVs, training records, certifications, etc.
14. Other responsibilities as assigned and as needed.

Skills

- Excellent verbal, written and interpersonal communications skills.
- Ability to efficiently organize and prioritize work within a multifaceted framework and deadlines;
- Excellent organizational and record-keeping skills with demonstrated attention to detail.
- Ability to work well in a team environment but also independently without significant oversight.

- Computer proficiency in MS Office 365, including Word, Excel, and PowerPoint; ability to learn new computer applications specific to the job function.

Experience

Minimum Qualifications: 1 year of related work experience with a basic knowledge of specified functional area, or an equivalent combination of education and work experience.

Preferred Qualifications: 2+ years of related work experience with a good understanding of specified functional area including typical clinical trial activities, Good Clinical Practice (GCP), and FDA regulations, or an equivalent combination of education and work experience. Basic knowledge of medical terminology.

Education/Certification

Minimum Qualifications: Associate's degree in scientific, healthcare or related technical field preferred.

Preferred Qualifications: Bachelor's degree, in scientific, healthcare, or related technical field. Clinical Research Certification (ACRP, SoCRA).

Physical Demands/Work Environment:

This position is home-based, however overnight travel for meetings and/or trainings may be expected on occasion.