

**Title of Job: *Clinical Research Coordinator***

**Description:** The Clinical Research Coordinator (CRC), as delegated by the principal investigator, executes and coordinates daily clinical research activities according to CRA's SOPs, GCP and FDA/ICH guidelines. 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. The Clinical Research Coordinator must also be able to perform clinical tasks (i.e. phlebotomy, EKGs, vital signs, etc.). CRCs typically perform tasks such as:

- Site preparation
- 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. Maintain RN License (if applicable).

**Status and Scope:** Reports to the Site Manager and/or the Region Manager.

**FLSA Status:** Non-Exempt

**Essential Job Duties:**

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

## Clinical Research Coordinator

3. Adheres to GCP, ICH, HIPAA, NIH, FDA Regulations and SOPs and maintain 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 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;
9. 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;
10. Performs appropriate research protocol procedures which may include, but are not limited to: vital signs, pregnancy tests, blood collection and processing, ECGs, alcohol breath tests and administers pain assessments;
11. Ensures study related reports and patient results are reviewed by an investigator in a timely manner;
12. Responsible for completion of case report forms, ensuring accuracy of data and reporting of adverse events to sponsor;
13. Dispenses investigational product and instructs subjects on usage and potential drug interactions;
14. Practical knowledge of document processes and reporting of SAEs, 1572s, CRFs, ICFs, etc.;
15. Prepares presentations to schedule training for physicians, nurses and staff on research protocol;
16. Provides patient education regarding disease process and involves patient and family in decision-making processes;
17. Generates reports for supervisor on patient enrollment and tracking;
18. Tabulates enrollment statistics;
19. Maintains accountability of own ongoing professional growth and development;
20. Performs necessary functions as approved by Clinical Research Advantage, for the conduct of clinical research;
21. Maintains strict confidentiality of patients, employees and company information at all times and adheres to HIPAA Guidelines;

*Confidential proprietary information of Clinical Research Advantage, Inc. ONLY – not to be duplicated.*

*Effective 4/1/2007*

## **Clinical Research Coordinator**

22. Responsible for drug accountability, maintaining logs and inventory of study product and supplies;
23. Coordinates and conducts pre-study, initiation, monitoring and close-out visits with the pharmaceutical representative, including completion of minutes and follow-up reports;
24. Maintains contact and interact with monitors and sponsors;
25. Works under direction of principal investigator;
26. Attends investigator meetings; and
27. May perform other duties not specifically listed in this job description as assigned by their immediate supervisor.