

Title of Job: Research Assistant

Description: The Research Assistant (RA), as delegated by the Site Manager, executes daily clinical research activities according to CRA's SOPs, GCP and FDA/ICH guidelines. Executes informed consent process and monitors patient status; collects and organizes research data; and handles much of the administrative responsibilities of the site to include: filing, answering the phones, rooming patients, making reminder calls, general site organization, etc. The Research Assistant must also be able to perform clinical tasks (i.e. phlebotomy, EKGs, vital signs, etc.).

Educational Qualifications: Certified Medical Assistant or a BA/BS in a science related field. More than 1 year experience in clinical research may be substituted.

Experience/Training:

- Medical Assistant Certification;
- Phlebotomy and EKG experience;
- CPR and blood pressure certification;
- Familiarity with GCP and FDA/ICH regulations;
- Good knowledge of medical terminology;
- Microsoft Office skills; and
- Completion of CRA's proficiency exams.

Licenses. etc: Maintains CPR certification, if an MA requires certification

Status and Scope: Reports to the Lead Clinical Research Coordinator and/or the Site Manager.

FLSA Status: Non-Exempt

Essential Job Duties:

1. Excellent written, oral, interpersonal communication skills, strong organizational talents with attention to detail;
2. Assists the Research Coordinators in their responsibilities by doing the following:
 - a. Performs basic screening of patients for study enrollment;
 - b. Enrolls patients in studies;
 - c. Performs patient follow-up visits;
 - d. Documents study procedures in source clinic charts;
 - e. Updates and maintains required logs and charts;
 - f. Prepares schedules;
 - g. Organizes work area;
 - h. Performing audits for quality control purposes;
 - i. Accurately processes and sends lab specimens per protocol specifications;
 - j. Completes case report forms ensuring accuracy of data and reporting of adverse events to sponsor;
 - k. Draws blood, takes vital signs, accurately completes EKG tests; and

Research Assistant

3. Becomes thoroughly familiar with the protocol, case report form, informed consent, source documentation and patient diary (when applicable), for the research studies;
4. Adhere to GCP, ICH, HIPAA, FDA Regulations and SOPs and maintain ongoing regulatory documents;
5. Ensures study related reports and patient results are reviewed by the Research Coordinator and/or investigator in a timely manner;
6. Generates reports for supervisor on patient enrollment and tracking;
7. Maintains accountability of own ongoing professional growth and development;
8. Performs necessary functions as approved by Clinical Research Advantage, for the conduct of clinical research;
9. Maintains strict confidentiality of patients, employees and company information at all times and adheres to HIPAA Guidelines; and
10. May perform other duties not specifically listed in this job description as assigned by their immediate supervisor.