Job Description

Position Title: **Sr. Clinical Research Associate**

Reports to: **Clinical Program Manager**

Department: **Clinical**

PURPOSE OF JOB: The Sr. CRA, with support from clinical project manager, is responsible for onsite monitoring duties for clinical trials, according to Aerin Medical Standard Operating Procedures, FDA/ICH guidelines and GCP, including Pre-study, Site Initiation, Routine Monitoring and Close-out Visits. He/She will be responsible for conducting the following essential duties with supervision from clinical director and project manager.

MAJOR DUTIES AND RESPONSIBILITIES:

- Verify that the research site personnel, including the investigators, are conducting the study according to the clinical protocol, "Good Clinical Practices," and regulatory requirements.
- Identify adverse events from research site staff and under the guidance of clinical project manager ensure appropriate reporting requirements are met.
- Verify that the data in the Case Report Forms (CRFs/eCRFs) are in agreement with the source documents (source data verification).
- Review accuracy and completeness of site records (site study file, query resolution, and other data collection tools).
- Verify Investigational Product accountability.
- Conduct routine monitoring visits with support from Clinical Project Manager and/or Director of Clinical Affairs.
- Prepare sections of the study site manual of operations as delegated by Clinical Project Manager.
- Support in drafting informed consent.
- Complete delegated clinical project deliverables per schedule.
- Assist clinical project manager to ensure audit-readiness of sponsor and investigative site files.
- Communicate relevant information to the clinical director and project manager in a timely manner.
- Contact sites on a consistent basis to assess study compliance.
- Track screening and enrollment and identify/report issues to the clinical project manager.
- Assist with the organization and administrative support of Investigator Meetings.
- Generate status reports process payments, maintain device and regulatory document tracking systems, patient and Case Report Form (CRF) files, required regulatory documents, and central files.
- Collect and track regulatory documents (e.g., confidentiality disclosures, IRB approvals, investigator agreements, contracts, study/project annual reports and financial disclosures) to/from study sites using company specific database.
- Able to show good judgment with interaction with external customers.
- Support development of clinical research forms, questionnaires, trackers and templates.
- Contribute to the creation and maintenance of study materials for clinical studies, including but not limited to site and CRA training materials, study binders, plans, study registration and other process descriptions, presentations, and reports.

Aerin MEDICAL

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EDUCATION REQUIREMENTS:

- Bachelor's degree or diploma in Science, Engineering, Quality or similar discipline

EXPERIENCE REQUIREMENTS:

- Minimum of 2 years' experience in clinical research

OTHER QUALIFICATIONS:

- Good oral and written communication skills, with the ability to communicate effectively with medical personnel
- Proven flexibility and adaptability
- Ability to work collaboratively in a team or independently as required
- Skilled with Microsoft Office with the ability to learn appropriate software and internet-based programs
- Ability to travel up to 40%
- Authorization to work in the US for any employer