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Job Title:	Clinical Research Associate I
Reports To:	Clinical Study Manager
Location:	900 Long Lake Road, New Brighton, Minnesota
Date:	2021 Apr 20

Purpose/Role

The Clinical Research Associate I is responsible for study files and documentation, payments and tracking of agreements, and various study administration responsibilities. The CRA-I works closely with the clinical team to meet study objectives.

Position Description

- Study Documents:
  - Assists with printing, organizing, compiling, and distributing clinical study documents including site Regulatory Binders and documentation needed for site initiation visits
  - Sends reports to sites such as upcoming subject visits, etc.
  - Maintains site/sponsor contact lists for each assigned study
  - Coordinates mass mailings
  - Assists in preparation of study newsletters, case report forms (CRFs), tracking tools, worksheets, laminated tools for sites, and pocket protocols
  - Prepares monitoring packets for monitoring visits
  - Participates in the testing of CRFs and the database
  - Performs center activation tracking ensuring receipt of appropriate study documentation, agreements, and approvals
  - Sends documentation for translation, as needed
  - Prepares requested documentation for Clinical Events Committee/Data and Safety Monitoring Board (CEC/DSMB) meetings
- Payments and Agreements:
  - Processes payments including ensuring an agreement is in place to allow payment, the amount is accurate based on the agreement, obtaining appropriate authorization signatures, tracking of, and providing payment status reports to sites and clinical personnel and accounts payable as requested
  - Verifies that agreements have been finalized and executed properly (e.g., correct agreement has been received, and proper signatures have been obtained)
  - Tracks agreement/insurance expirations and renewals
- Study Files:
  - Sets up, organizes and maintains trial master files including subject files, agreements and payment files
  - Reviews regulatory document for completeness prior to filing
  - Maintains regulatory binders for each site of each assigned study. This includes correspondence (including emails), ethics committee/institutional review board/research ethics board (EC/IRB/REB) approvals and renewals, curricula vitae (CVs) and any other required documents
  - Performs periodic audits of clinical study files for completeness

- Device Inventory:
    - Maintains device inventory records including usage and expiration dates, if applicable to the assigned study
- Completes special projects/other duties as assigned
- Assists with planning, logistics, meeting locations, and travel arrangements for clinical study meetings
- Serves as a liaison between clinical personnel, site personnel, and field staff to include sending of documentation requested and forwarding study related calls, etc., as needed
- Supports data management activities

Qualifications

Education:

- Associate degree in a health sciences field or related; 4 yr. degree preferable

Experience:

- 1-3 years of clinical study administration or related experience (e.g., Clinical Research Coordinator)
- Experience in cardiovascular/heart valve disease is highly desired
- Experience with medical device clinical studies

Skills:

- Organizational skills and attention to detail
- Works independently and in a team environment
- Experience coordinating, prioritizing, and setting timelines for multiple tasks
- Able to communicate effectively, both orally and in writing
- Proficient computer skills (Microsoft Word, Excel, PowerPoint, etc.)
- Knowledge of medical terminology
- Knowledge of medical device regulations and compliance guidelines for clinical studies
- Knowledge of Good Clinical Practice (GCPs)

Other:

- Light work, exerting up to 20 lbs. of force or less and lifting binders up to 10 lbs.
- Sit or stand for 8-10 hours per day

PLEASE NOTE THAT ONLY APPLICANTS LOCAL TO THE TWIN CITIES AREA WILL BE CONSIDERED.