Job Title:	Clinical Research Associate I
Reports To:	Clinical Study Manager
Location:	900 Long Lake Road, New Brighton, MN 55112
Date:	2017 December 8

Purpose/Role

A brief description of the primary responsibilities for which the employee is accountable

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

A listing of the deliverables to be accomplished, including specific duties/activities that make up the job

- 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, 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
- 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 and provides payment status reports to clinical personnel
  - Verifies that agreements have been finalized and executed properly (e.g., correct agreement has been received, and proper signatures have been obtained)
  - Tracks agreement expirations and renewals
- Study Files:
  - Sets up, organizes and maintains trial master files including subject files, agreements and payment files
  - Maintains regulatory binders for each site of each assigned study. This includes correspondence (including emails), IRB/EC approvals and renewals, 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
- 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

Represents the desired qualifications but may not reflect the employee's existing qualifications

Education:

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

Experience:

- 1-3 years of clinical study administration or related experience
- 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
- 10% travel may be required

Please note that only candidates local to the TWIN CITIES will be considered.

The purpose of this description is to provide a concise statement of the major responsibilities of this position in a standardized format. It is not intended to describe all the elements of the work that may be performed and should not serve as the sole criteria for personnel decisions and action.

Approvals:

_____ _____

Employee (signature) Date

_____ _____

Manager (signature) Date