Clinical Research Study Coordinator

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About the Position:

The Clinical Research Study Coordinator will ensure that clinical research projects are translated into active clinical protocols. In particular, the incumbent be responsible for all research activities from submission of regulatory documents, preparation of clinical study forms, recruitment of research subjects and conduct of clinical studies as well as data collection, monitoring and entry. The incumbent will adhere to agreed upon project priorities, timings, quality specifications and all relevant regulations including SOPs and policies as well as GCP.

The Clinical Research Study Coordinator is expected to be fully capable of performing all the roles encompassed by this position as well as additional relevant tasks as required by the Principal Investigator. Other activities, special projects and assignments may be given as required. As a result, the percentage of time spent across roles for which the Clinical Research Study Coordinator is responsible for or assisting with will vary depending on project assignments, current development projects, staffing and the requirements within the organization as a whole.

Principal Responsibilities:

- Clinical Research Study Coordinator
  The incumbent will be responsible for all study management aspects of the Principal Investigator’s clinical research portfolio including but not limited to all of the tasks specified below.

- Study concept, planning and strategy phase:
  The incumbent will be responsible for budgeting for studies, assisting with proposal submission, assessment of resources and personnel required; and the development of study timelines.

- Study Initiation phase:
  The incumbent is responsible for essential document development (e.g. study consent forms, advertising materials), and all protocol materials; assessing facility requirements and liaising with appropriate departments and centers; ensuring the development of subject recruitment; planning clinical study and ordering supplies; review and approval of data management plan.
- Study Management/Conduct Phase:
The incumbent will be responsible for study enrollment management/tracking (e.g. contingency planning and implementation budgetary management; ongoing management of protocol deviations; ongoing review of study data and data cleaning process. The incumbent will be expected to personally conduct certain aspects of human studies, e.g. interviews, simple clinical procedures.

- Analysis and Presentation Phase:
The incumbent will oversee database lock activities and data analyses with Principal Investigator; will assist with preparation of tables, figures, slides and manuscripts reporting study results.

- Other roles:
Other roles may be allocated as appropriate to the incumbent as required.

Preferred candidates will have:

* BS, BA or MS with clinical research experience
* Knowledge of scientific methods, research design and regulatory issues pertaining to human subjects research.