Children's Hospital Boston
life-changing care world-changing research

The Clinical Research Center

Clinical Research Trial Manager

The Clinical Research Trial Manager is responsible for collaborating with Principal Investigators for the development and management of research studies across departments and institutions. The CTM will serve as liaison to maintain communication between study staff and Clinical Research Center personnel. Candidates should have previous experience and training to manage, problem solve, provide guidance and implement procedures for clinical research projects, while interfacing directly with Principal Investigators and study sponsors to manage and advise on trial related activities for large or multicenter protocols. The CTM will manage trial data collection for IND/IDE studies, organization and reporting as required by FDA, including providing data safety reports, updates and monitoring activities utilizing the resources of the Clinical Research Center data managers, statisticians, clinical research specialists, and clinical

General Summary

- Leads and manages the work of clinical research projects.
- Serves as Clinical Research Trial Manager for one or more large, clinical studies.
- Consultation and Collaboration: Independently collaborates and consults with investigators and their staff on the design, development, and conduct of their clinical research studies and on clinical research best practices.
- Works with study investigators and statisticians to plan analyses, clean and verify data and facilitate preparation of datasets for analyses.
- Collaborates directly with CHB investigators and CRP scientific staff on the development and writing of grants and study protocols.
- Develops curriculum, conducts lectures, and directs courses as part of the CRP's educational efforts to train clinical investigators and study staff in clinical research regulations and best practices.
- Leads design and development of data management and data monitoring tools and procedures and supervises data management staff and activities in compliance with GCP and program standards.

Minimum Knowledge and Skills required by the Job

- Work requires the knowledge of theories, principles and concepts typically acquired through completion of a Master's degree in health science, public health, epidemiology or a closely related field, including course work in biostatistics or computerized analytic methods plus 5 or more years of project management experience in public health, community health or clinical research settings.
- Proven expertise in staff supervision and management of complex clinical studies and FDA regulated trials in academic settings, protocol writing, budget development and oversight for NIH and philanthropic grants.
- In-depth knowledge of clinical research best practices.

  Proven experience and knowledge sufficient to manage the utilization of complex research, scientific and analytic methods.
- Knowledge of grant and protocol writing and development.
- In-depth knowledge of human subject protections regulations (i.e., OHRP, FDA and ICH GCPs).

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For more information or to apply please visit the Children's Hospital Careers Page and search for job ID 26679