CTO Medical Director Job Description

Developed by the AACI CRI CTO Medical Director Forum

January 2021

The medical director provides overall direction and oversight in the clinical operations of the clinical trials office (CTO). The medical director works with cancer center leadership and the CTO operations/administrative director to develop strategic plans for the CTO and provide quality service to all stakeholders including study participants, physician investigators, regulatory authorities, and trial sponsors. The CTO operations/administrative director should report to the CTO medical director.

The CTO medical director will be an experienced physician and active clinical researcher at the academic rank of associate professor or professor. They will have extensive experience as a clinical trial investigator and have completed all appropriate training. They will be knowledgeable of research operations including clinical conduct, regulatory compliance, budget development, contracting, and strategic planning. They will be appointed by and accountable to the relevant associate director or similarly designated cancer center leader at the cancer center director's discretion. The estimated time commitment is 30-50 percent effort.

Primary Responsibilities:

- Act as the primary liaison between faculty, departments, and health care system partners regarding clinical research and will work to identify areas of improvement and resolve conflicts
- Review and resolve or escalate clinical, regulatory, or budget issues with investigators, service line, other departments, and internal/external partners
- Serve as the CTO spokesperson for the cancer center
- Actively participate in the cancer center clinical research oversight committee, comprised of key cancer center stakeholders responsible for the success of the clinical research mission
- Oversight of the CTO operations/administrative director with respect to the operations of the CTO, including management of staff job descriptions, workload assessment, hiring, and performance evaluations
- Facilitate the successful onboarding of investigators and research staff, and provide ongoing support for career development
- Help determine when and how resources should be reallocated and communicate these plans with investigators and cancer center leadership.
- Provide guidance to disease research teams on prioritization of clinical trials based on catchment area, institutional priorities, and trial performance
- Work with CTO operations/administrative director and all other relevant stakeholders to optimize timely trial activation and high-quality study conduct
- Work with CTO operations/administrative director to develop and monitor annual CTO budget and advocate for additional resources when needed to address changing workloads and investigator needs
- Facilitate integration of CTO activities with biostatistics, investigational drug pharmacy, clinical trial specimen processing, the Protocol Review and Monitoring System (PRMS), and the Data & Safety Monitoring (DSM) system as appropriate
- Review internal and external audit/monitoring visit reports and work with the CTO staff to develop, implement, and monitor corrective action plans with specific focus on physician oversight and compliance; determine best methods for disseminating communications regarding corrective action plans with faculty and clinical staff
- Adhere to NCI P30 Cancer Center Support Grant (CCSG) guidelines, actively engage in preparation of the written CCSG application and other necessary annual updates/non-competitive renewal submissions to NCI
- Provide periodic review, update, and oversee development of cancer center boilerplate language, processes, and other resources to support investigators pursuing grants utilizing CTO resources
- Provide oversight of the development and review of standard operating procedures (SOPs) for the CTO
- May provide or contribute to the annual performance evaluation of the CTO operations/administrative director