Duke University School of Medicine
Job Description for Faculty Director of the Duke Early Phase Research Unit
February 2022

The Faculty Director of the Duke Early Phase Research Unit (DEPRU) will report to the School of Medicine (SOM) Vice Dean of Clinical Research. This role will provide leadership and medical oversight for the DEPRU service center. This position includes both strategic and operational responsibilities that require significant professional effort on an ongoing basis.

The Faculty Director will collaborate closely with the DEPRU Medical Director, as well as the Duke Office of Clinical Research (DOCR) Associate Dean and Directors, and Research Administration Support Resource (RASR) for pre and post award management. The Faculty Director role includes:

Management and Leadership
- Build collaborations with department chairs, center/institute directors, and CRU directors to advance Duke’s involvement and leadership in early phase research
- Oversee unit operations to ensure the highest level of quality including both the safety of research participants and integrity of data
- Develop a high performance work culture in which unit staff (including nurses, clinical research coordinators, and other research staff) report high levels of job satisfaction and are highly regarded by the investigator community for their expertise, enthusiasm and customer-orientation
- Assess and implement operational processes and cost-effective technologies that enhance study conduct, leading to greater efficiency and fewer errors
- Communicate with sponsors for new opportunities
- Secure and manage a balanced portfolio of projects that allows the unit to be academically and financially self-sustaining
- Participate in the assessment of scientific, operational and financial feasibility of proposed studies
- Participate in go/no go decisions regarding specific project opportunities and intervene/assist with budgets, proposals, and financial and timeline negotiations as needed
- Collaborate with the DEPRU Clinical Research Unit (CRU) Advisory Board and the Vice Dean of Clinical Research to set the strategic vision for the unit

DEPRU CRU Director
- Serve as the Director of the DEPRU CRU
- Responsible for the scientific integrity, quality, academic productivity, regulatory compliance, and financial solvency of all clinical research conducted under the DEPRU CRU oversight
- Participate in SOM CRU Directors and CRU Advisory Council meetings

General Faculty Director Responsibilities
• Promote an environment in which the Principal Investigators for each study retain independent judgment and responsibility for their clinical research; address issues and concerns related to Principal Investigator responsibilities and escalate
• Maintain awareness of all studies utilizing DEPRU space, equipment, and/or staffing
• Review all non-routine proposed usage for each study to ensure appropriateness
• In collaboration with DOCR and Nurse Manager, provide proper allocation of resources and ensure policies are in place and followed
• Monitor the quality and appropriateness of services provided

Principal Investigator for Select Studies Beyond the Faculty Administrator Role
• May serve as Principal Investigator on studies, in which case effort will be covered by the study
• Develop and write protocols
• Communicate with the study sponsor
• Participate in study planning and startup and leading this activity as needed
• Actively engage in investigator role during study conduct, including medical monitoring
• Review study documents (e.g. statistical analysis plans, pharmacokinetic reports, and clinical study reports)
• Manuscript preparation and review and ensure a high level of publication

Regulatory and Compliance
• Maintain required certifications and licensure
• Ensure adequate supervision of APPs (physician assistants and nurse practitioners) including regular performance reviews and feedback, ensuring proper clinical research and medical training and continuing education
• Ensure staff and facility’s compliance with federal and state regulations and codes
• Serve as the medical representative during regulatory compliance audits and inspections

Education and Training
• Provide relevant educational programs for unit staff on general early-phase clinical trial conduct
• In collaboration with the Medical Director and DOCR Directors, leverage the DEPRU infrastructures for training of students, residents, and fellows on clinical trial conduct

Qualifications
This position requires a doctorate degree (MD, DO) and credentials to qualify for appointment to the faculty in one of the School of Medicine Departments.

A minimum of two years’ direct experience and leadership is required in the following areas
• Clinical research implementation & management for federally and industry-sponsored research
• Effective oversight of regulatory and ethical aspects of research
• Effective personnel, budgetary and resource management skills

Special competencies/credentials include
• Strong organizational and interpersonal skills with demonstrated supervisory and communication skills.
• Ability to work with faculty and institutional administration in a collaborative manner across Departments, SOM, Centers, and Institutes

Duke University School of Medicine is very interested in a diverse candidate pool and encourages applications from women and those from other groups underrepresented in medicine.

Interested candidates should submit a statement of interest and a Curriculum Vitae to somclinicalresearch@duke.edu by February 28, 2022.

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