Duke University School of Nursing
Job Description
HR Job Title: Research Program Leader
Job Code: 1280
Job Level: 58
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Occupational Summary

The Research Program Leader will be responsible for a broad range of duties related to planning, organizing, executing, and monitoring the implementation and ongoing operations of complex research projects in the RISE Lab. The portfolio of projects spans community-engaged health equity work with an emphasis often on biopsychosocial determinants of health among sexual and gender minority populations and people living with HIV.   This position will serve as the operational lead for a portfolio of projects, provide oversight and day to day management of study teams, lead management of preaward activities, and draft and revise scientific writing for a variety of contexts (grant proposal, abstracts/manuscripts and public dissemination products).

Supervisor

This position reports to the SON Research Practice Manager.

Work Performed
 Operations:

For complex scenarios, recognizes when agreements are necessary within the research program. Facilitates the process by coordinating with study teams and appropriate Duke offices. Serves as an expert resource to multiple study teams/research program regarding regulatory and institutional policies and processes. Independently navigates conversations with foreign agencies and study teams to develop or obtain the required documentation for compliance with international regulations. May assist others with ensuring regulatory compliance with international studies. Provides direction to multiple study teams/research program to prepare for study monitoring and audit visits. Provides oversight, training, and expertise to multiple study teams/research program regarding participant level documentation for all studies, including those that are complex in nature (e.g., procedural and interventional studies) and/or require DUHS billing. Serves as an expert resource for multiple study teams/research program for participant retention. Liaises with other resources at Duke to optimize retention rates. Develops and oversees the implementation of strategies for meeting recruitment goals for the research program(s). Provides training. Serves as an expert to research program team members in the area of screening. May provide oversight and conduct training in this area. Develops, oversees adherence, and trains in the use and development of SOPs across multiple study teams/research program(s). Creates, optimizes, and oversees the systems for managing specimens for multiple study teams/research program. Serves as an expert resource and trainer in specimen collection, processing, preparation, shipping and maintenance. Provides expertise to research program team members in study level documentation. Provides oversight and training and lends expertise to research program. Serves as an expert resource and trainer to multiple study teams/research program for preparing and conducting complex study visits, developing tools, and implementing operational plans. Prepares for and leads

research program meetings. Ensures good communication within the research program, including mentoring staff to improve communication strategies.

Ethics:

Ensures that multiple study teams/research program team members are appropriately identifying and documenting adverse event information. Provides oversight and training to multiple study teams/research program team members who conduct and document consent for participants for all types of studies, including those that are complex in nature and/or require any orders in Maestro Care. May serve as an expert resource with regard to conducting and documenting consent including liaising with and being knowledgeable about other resources at Duke. Provides oversight and training to multiple study teams/research program team members who develop the consent plan and document. Serves as an expert resource with regard to developing consent plans and documents for participants in a variety of studies. Provides oversight and training to multiple study teams/research program team members who develop and submit documentation and information for IRB review. Provides oversight and training to multiple study teams/research program team members who prepare and submit documents needed for regulatory and safety reporting to sponsors and other agencies.

Data:

Selects and implements data capture methods appropriate for the research program. Serves as an expert in designing ECRFs and EDCs to collect data according to protocols and research program processes. Oversees the process of QA, data corrections, and queries used within multiple study teams/the research program, including creating and using QA protocols, queries, summaries, and reports. Recognizes trends, and recommends strategies to improve processes or retrain staff. Serves as an expert data corrections, queries, and quality assurance resource, including liaising with and being knowledgeable about other related resources at Duke. Develops and implements protocols for research program that include strategies and processes to ensure data security and provenance. Serves as an expert data provenance and security resource, including liaising with and being knowledgeable about other related resources at Duke. Serves as an expert resource to multiple study teams/research program with regard to mapping data flow. Predicts areas of vulnerability in the data flow plan. Determines areas where data provenance may be compromised, and helps study teams/research program staff work through solutions. Ensures that study teams are familiar with data flow resources at Duke. Seeks out, integrates, and applies new technical knowledge towards innovation and performance improvement for multiple research teams/research program, as relevant.

Science:

Independently develops funding proposals and grants, including leading the drafting of research aims, background, methods, etc. Independently reviews articles, synthesizes the literature, and uses to assist in the development of manuscripts or grant proposals. Independently develops protocols for multiple complex investigator-initiated studies within the research program. Uses expertise in research design to provide significant contribution to protocols or research proposals. Provides significant contribution or leadership on accepted, peer-reviewed publication or conference presentation. Mentors others in this area.

Study and Site Management:

Mentors, trains, and oversees activities related to how teams communicate with sponsors and/or CROs. Oversees activities related to site visits. Oversees use of systems and system reports to manage research participants' activities and tracking/marking financial milestones. Oversees use of systems and system reports to manage research protocol activities and maintaining current protocol information. Makes feasibility recommendations for multiple study teams/research program. Develops and oversees processes to determine participation in trials. Oversees management of resources (staff, supplies, equipment) for multiple study teams/research program. May manage the budget for research studies. For multiple study teams, ensures that studies are conducted in compliance with institutional requirements and other policies. Oversees implementation of operational plans across research program, including at multiple sites. Develops and implements closeout procedures for multiple studies across multiple teams.

Leadership:

Encourages staff to take part in professional development opportunities. Keeps current with advances in the scientific area and considers the impact on the research program. Keeps self and team current with research updates by attending external offerings; applies learned material on the job. Plays key/leadership role on committees and workgroups. Navigates processes and people involved in Duke clinical research, demonstrates the organizational awareness, and has the interpersonal skills necessary to get work done efficiently. Develops and implements solutions that work within the existing leadership or organizational structure. Demonstrates resilience and actively facilitates the research program through change. Uses advanced subject matter expertise in the therapeutic area or clinical research to solve complex problems or foster innovation within the research program. Communicates effectively with others, regardless of reporting relationship, to accomplish shared work objectives. Establishes and assigns the activities of the research program team members to accomplish the study goals.

Description of Portfolio Responsibilities: (Effort 100%):

Determines short- and long-term goals of the research program/shared resource in collaboration with investigator(s). Identifies research programs/shared resources gaps, constraints, needs, and milestones; helps develop operational sustainability plan and communicates with PI to plan necessary resourcing. Manages and documents all aspects of research project lifecycle including: initiation, planning, executing, monitoring, and closing. Directs project staff in the execution of project activities in accordance with project plan and timeline. Communicates project/program progress with all major stakeholders and adjust plans and timelines according to feedback. Manages the research program or shared resource operations. Monitors and adheres to the established budget, and assists with budget development. Ensures that institutional communications are shared with research program staff and faculty. Maintains communication within program and with other departments or offices to accomplish the program objectives. Manages, mentors, and/or trains staff. Maintains an awareness of regulations, policies, and resources relevant to research and therapeutic area and applies knowledge to the development and execution of operational plan. Ensures that all programs and projects are compliant with all relevant regulations and policies. Provides guidance to staff on best practices in research study or program conduct (e.g., recruitment, consenting, study documentation, program evaluation, data capture, etc.). Provides intellectual contribution to the research program or shared resource, including

developing and editing research proposals and manuscripts. Represents research program or shared resource on behalf of the PI at internal and external meetings.

The Research Program Manager will be responsible for a broad range of duties related to planning, organizing, executing, and monitoring the implementation and ongoing operations of a complex research portfolio in the RISE Lab. The portfolio of projects spans community-engaged health equity work with an emphasis often on biopsychosocial determinants of health among sexual and gender minority populations and people living with HIV.

The research portfolio currently consists of 12 projects for the RISE Lab, including studies that rely on an external IRB, and multicenter studies that will rely on the DUHS IRB. The portfolio of projects spans community-engaged health equity work with an emphasis often on biopsychosocial determinants of health among sexual and gender minority populations and people living with HIV.

This person will manage three CRCs, one staff specialist and a graduate student research assistant or data manager. The lab has multiple multi-million dollar federal grants.

In addition to managing internal staff, this position will coordinate and support subcontractors and stakeholders, and coordinate work efforts to ensure effective communication between colleagues, community partners and research collaborators. This position is responsible for drafting and revising scientific writing for grant proposals, abstracts/manuscripts and public dissemination products.

Perform other related and requested duties incidental to the work described herein.

Required Qualifications at this Level
Education/Training
 1.Completion of a Bachelor's degree 2. Completion of an Associates degree plus a minimum of two years relevant experience (e.g., research, clinical, interaction with study population, program coordination)

Experience
Preferred candidates will have a minimum of 3 years of experience in project coordination related to research/evaluation/program management or health equity/community engagement. Applicant should be able to develop timelines and take guidance from a PI to develop budgets and scopes of work; experience on a research team with grant writing is preferred. Applicants must be able to prioritize competing demands and work independently and efficiently across a growing research team. Attention to detail, problem solving, and a demonstrated ability to work and collaborate within and across teams both inside and outside the organization is essential.

Preferred candidate will have a PhD in public health, anthropology, sociology, or related field. Prefer at least 3 years of experience managing large multi-site research grants as well as experience with at least one of the following software: Endnote, Atlas.ti, Stata or SAS. Prefer at least 3 years of experience working on research projects related to sexual or gender minority health.

Skills
Applicant should have organizational and management skills as well as interpersonal and communication skills. Professionalism, maturity, and experience are expected in working with people

from a variety of cultural identities, affiliations, and settings as our portfolio of projects and teams are often community- based and working with health equity issues and under resourced contexts. Applicant should have experience with critically reviewing and summarizing literature, interpreting research results, and drafting reports and scholarly products in educational or professional environment. Must have flexibility in work schedule. Minimal travel required (5%).