



**Clinical Research Unit (CRU) Director (20 to 30% time)
Position Description**

The CRU Director has overall responsibility for ensuring the integrity, financial accountability, regulatory compliance, quality, and academic productivity of clinical and translational human subjects' research taking place within their unit. The CRU Director will report to the Vice Chair for Research (VCR) and will work collaboratively with the VCR and Department Chair to ensure all Duke Psychiatry CRU activities are carried out in an efficient and timely manner.

The selected candidate will possess a history of successful grant funding and a collaborative approach to working with colleagues within the department and outside. This position requires strong communication skills, responsiveness, flexibility, team leadership skills, ability to mentor on the practice of GCP, and timely sharing of information with investigators.

The CRU Director will work with the Research Program Manager to oversee to the North Pavilion 3rd floor Clinical Research Facility. This individual will promote—with the VCR, Chair, and CRU team—a culture of research accountability and integrity.

The CRU Director provides oversight to CRU-related activities conducted by the Research Practice Manager and input to the Financial Practice Manager. The CRU Director will also work closely with the Director of Research Administration to provide seamless support to research faculty and staff for pre and post award activities balanced with the management of compliance and financial risk. The CRU Director and Director of Research Administration will have individual and shared responsibilities with oversight of the CRU team.

Description of responsibilities:

- Ensure that the unit provides support and training to researchers and staff conducting clinical and translational research involving human subjects research.
- Ensure that unit processes are in place with written Standard Operating Procedures to encourage compliance with local, regional, and national regulations and with institutional policies and procedures related to the conduct of clinical research.
- Ensure timely and quality process to review CRU protocols that are reviewed by the DUHS IRB. Process includes an evaluation of:
 - Operational and clinical feasibility of protocols and appropriate expertise to conduct the protocol.
 - Study personnel training and appropriateness to role.
 - Financial feasibility.
 - Safety, welfare, and appropriate care of research participants and their data.
 - Appropriateness of study plan to research question.
 - Ensure there are no IRB deferrals.

- Convene and solicit regular, written feedback and input from Duke Psychiatry investigators & staff within the CRU to improve processes and practices.
- Identify responsibility around audits – internal or external.
- In coordination with the Department Chair, VC Research, and other CRU staff, forecast resource needs for the unit; oversee the preparation and management of the CRU budget.
- Oversight and approval of changes and/or waivers to the CRU fee structure, payment terms, holdbacks, etc.
- Receive, review, and prepare reports to monitor the portfolio of the CRU, to include the CRU Annual Report; regularly review key metrics and resource needs with and VC Research and Chair.
- Oversight of the Department’s Scientific Culture and Accountability Plan (SCAP)
- Oversight of the implementation and support of new institutional or SoM initiatives (e.g., onCore, iRIS).
- Represent the CRU at regular meetings; disseminate important information to CRU staff, investigators, and research staff. These meetings include, but are not limited to, attending the Quarterly CRU Advisory Council meetings and monthly meetings for the CRU Medical Directors.
- Escalate issues to leadership as appropriate.
- Active participation and attendance at the monthly CRU Director’s meeting, the Quarterly CRU Advisory Council, and working closely with the institution research administrative teams (i.e. DOCR, ASSIST, and Dean’s Research Office).
- Lead operations of the North Pavilion 3rd floor Clinical Research Facility including establishing procedures to ensure compliance with best practices and regulatory requirements, monitoring the utilization and scheduling of rooms, and providing regular updates to faculty on developments or changes to the Clinical Research Facility.
- Oversee the Department’s CRU website content and provides input for updates.
- Lead by example by exemplifying outstanding human research practice.
- In collaboration with the Research Practice Manager, manage and lead the CRU Core team and attend weekly meetings.
- Coordinate and contribute to the Psychiatry Biostatistics Epidemiology Research & Design (Psych BERD) core.
- Identify ongoing challenges in clinical research in Psychiatry and develop initiatives to address these challenges.
- Assist faculty in the development of high quality, rigorously designed research applications.
- Ensuring the appropriate review of the scientific merit of trials and the development and execution of a credible financial plan. Manage the protocol review, approval and prioritization process. Ensure the academic integrity and output of research related publications and presentations.

Interested candidates should send a cover letter, their CV, and three references to Jonathan Posner, MD, Vice Chair for Research (jonathan.posner@duke.edu)