

# Clinical Research Unit Charter



Name of CRU: Department of Medicine

Date Form Completed: August 1, 2017

CRU Medical Director Signature: \_\_\_\_\_

Unit Head Signature: \_\_\_\_\_

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## 1. Scope of Research within the CRU:

The scope of the Medicine CRU includes all clinical research studies involving human subjects at Duke University Medical Center within the Center for Applied Genomics and Precision Medicine, Divisions of Endocrinology, General Internal Medicine, Gastroenterology, Geriatrics and the Center for Aging, Hematology, Infectious Diseases, Rheumatology, Nephrology, Pulmonary and Allergy and Critical Care Medicine, Duke Human Vaccine Institute (DHVI), and Duke Molecular Physiology Institute (DMPI). The Medicine CRU provides oversight and support for clinical research in which Duke Health is the investigative site for the research and/or a Duke Health faculty member is responsible for direct interventions, observations, surveys, or interactions with Duke patients, and or Duke study participants, the use of biologic specimens from Duke patients and access to confidential, private information from Duke patients.

The CRU ensures a core of skilled individuals to manage the clinical research activities, ensure the necessary training of investigators, research coordinators, and other study personnel and provide both financial and research practice support and oversight to ensure compliance with all local, state and federal regulations and institutional policies and procedures.

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## 2. Key Personnel:

Medical Director: Susanna Naggie, MD, MHS

Associate Director: Sara Patillo, MSHS, CCRP, PMP

CRU Research Practice Manager: Elaine Dowdy MSW, LCSW, CCRC

CRU Assistant Research Practice Managers:

Kristy Averette, RN, BSN, CCRP

Tammy Bishop, RN, MSN, CCRP, CCRC

Vlayka Liotcheva, PhD

CRU Financial Practice Manager: Nancy Mace

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## 3. Define Clusters and Leadership within Clusters:

Each division/institute/center within the CRU will function as its own cluster. Each cluster will have its own Medical Director and CRU ARPM.

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Division/Institute	Medical Director	DOM ARPM
Endocrinology	Tom Weber, MD	Kristy Averette
Geriatrics	Kenneth Schmader, MD	Kristy Averette
Infectious Diseases	Richard Drew, Pharm.D.	Kristy Averette
	Mehri McKellar, MD	
Rheumatology	E. William St. Clair, MD - Terry Terrant, MD	Kristy Averette
Nephrology	John Middleton, MD	Tammy Bishop
General Internal Medicine	Hayden Bosworth, PhD	Tammy Bishop
Gastroenterology	Andrew Muir, MD	Tammy Bishop
Hematology	Nirmish Shah, MD	Vlayka Liotcheva
Pulmonary, Allergy, and Critical Care Medicine	Loretta Que, MD	Vlayka Liotcheva
Center for Applied Genomics and Precision Medicine (CAGPM)	Tim Veldman, Ph.D., Chris Woods, MD, MHS	Kristy Averette
Duke Molecular Physiology Institute (DMPI)	William E. Kraus, MD	Vlayka Liotcheva
Duke Human Vaccine Institute (DHVI)	Tony Moody, MD	Kristy Averette

## 4. Faculty Advisory Board

### Composition:

The Medicine CRU Faculty Advisory Board (FAB) includes the medical directors from each division/institute/center. The Medicine CRU FAB is chaired by the CRU Medical Director and will meet quarterly.

### Function:

The Medicine CRU FAB will provide direction to and consult with the CRU leadership team to help carry out the CRU mission, to improve the conduct of human subjects research, and to maintain a forward thinking

vision for the unit. The Medicine CRU FAB will be asked to review and provide recommendations regarding departmental standards and systems for the conduct of clinical research and new initiatives. The role of the FAB and its members is expected to include:

- Input on and review of new standard operation procedures (SOPs) for the Medicine CRU
- Assist in the development of process-oriented systems that will improve the support for the conduct of clinical research in DOM
- Advise CRU and DoM leadership regarding the appropriate establishment of CRU and divisional administrative fees to support clinical research administration as well as the appropriate distribution of margin or loss from clinical research studies
- Input on and review of the CRU research portfolio
- Provide vision for the unit that represents the interests of all clusters, streamlines the conduct of research while protecting human subjects
- Manage COI or breaches of ethical conduct

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## 5. CRU Governance and Financial Plan:

The Medicine CRU reports to the Chair of the Department of Medicine through the Medical Director and Department administrative structure. The cost of the Medicine CRU staff and operations are covered partly by the Medicine Chair's office and partly by an allocation to each division/center/institute that fall under the oversight of the DOM CRU. Factors included in the allocation are: the size of the research portfolio (heavily weighted towards full board reviewed protocols) and the size of the research staff. The allocation will be directed to the divisional HUB code which will contain the SOM mandated management fee (minimum of 10%) and the residuals from all studies at closeout (no less than 25%).

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## 6. CRU Stakeholders:

The Medicine CRU stakeholders include but are not limited to: patients who participate in CRU studies, investigative teams who conduct this research and all Duke Health entities with whom they interface. These include but are not limited to, the departments of Anesthesiology, Oncology, Pediatrics, Pharmacy and Radiology, Clinical Support Units (CSUs), Centers and Institutes, Duke Regional Hospital, Duke Health Raleigh, the Duke Clinical Enterprise and Hospital, the NIH, all trainees at Duke, all other academic organizations including the Duke DCRI and finally the offices of DOCR, IRB, ORC, ORA and OSP. External stakeholders would include the sponsoring organizations, as well as all the other academic institutions with whom our investigative teams collaborate.

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## 7. Communication Plan:

The Medicine CRU will communicate information via email, meetings and the Medicine website. Additionally, the Medicine CRU will cascade information regarding changes to institutional guidelines and policies as it pertains to the CRU, investigators and study personnel.

There are many standing meetings held to enhance communication, these include:

- Weekly CRU leadership team meetings
- Biweekly meeting with the FPM and team grant and contracts administrators (GCAs)
- Monthly meetings with the Medicine RPM and the division Lead Coordinators
- Monthly meetings between the Medical Director and the Chair
- As needed: one- on-one meetings with investigators and study team members
- Monthly meetings spanning the full financial and operation team

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Insert Organizational Chart:

DOM CRU RESEARCH ADMINISTRATION Leadership  
Operational Organizational Chart

