

Clinical Research Unit Charter

Duke University School of Medicine



DUKE UNIVERSITY SCHOOL OF MEDICINE

Name of CRU: **Duke Clinical Research Institute**

Date: 13 November 2014

CRU Director Signature: Lawrence H. Muhlbaier

Unit Head Signature: [Signature]

NOTE: Example or explanatory text in italics may be deleted.

1. Scope of Research within the CRU:

(Please list the division, department or sub-specialties/therapeutic areas of research that will be included in CRU. If applicable, address any common or frequent areas of overlap between the CRUs.)

The scope of research within the Duke Clinical Research Institute CRU includes faculty research activities and research studies conducted at DCRI led by a DCRI faculty (category A & B). In addition, the DCRI CRU will provide oversight of the Duke Translational Medicine Institute (DTMI) community projects.

The DCRI CRU will be responsible for the scientific integrity, quality, academic productivity, regulatory compliance, and financial solvency of all research projects conducted at the DCRI and DTMI community projects.

The scope of the DCRI CRU does not include

-- any studies with billing risk, or

-- those using Maestro Care to prospectively associate a patient with a study.

These will be addressed via the CRU from the Faculty PI's primary department.

DCRI CRU areas of research include: Cardiology; Hepatology/Gastroenterology; Endocrinology; Hematology; Nephrology; Oncology; Ophthalmology; Transplant Medicine; Women's Health; Geriatrics; Metabolic Bone Disease; Immunology and Inflammation Medicine; Infectious Diseases; Neurosciences Medicine; Otolaryngology; Pediatrics; Perioperative Medicine; Primary Care; Pulmonary Medicine; Clinical and Genetic Economics; Outcomes, Health Economics and Quality of Life; Quality Improvement initiatives.

2. Key Personnel:

Director: Lawrence H. "Doc" Muhlbaier, PhD

CRU Research Practice Manager: Simona Farcas

CRU Financial Practice Manager: David Hill

Other: N/A

3. Define Clusters & Leadership within Clusters;

DCRI Therapeutic Areas and Key Research Programs



Cardiology

John H. Alexander, MD, MHS, Director, Cardiovascular Research

Matthew Roe, MD, Director, Commercial Mega Trials

Clinical Trials

Director: John H. Alexander, MD, MHS

Operational Contact: David Hufner, Assistant Director, Clinical Operations

Global Outcomes Commercial Mega Trials

Director: Matthew Roe, MD

Operational Contact: Lisa Berdan, Director, Commercial Megatrials

Cardiovascular Devices

Co-Directors: Mitchell W. Krucoff, MD and David F. Kong, MD

Operational Contact: David Hufner, Assistant Director, Clinical Operations

CV Outcomes Research

Director: Adrian Hernandez, MD

Operational Contact: Elizabeth Fraulo, Assistant Director, CV Outcomes

Federal Government

Leader: Eric Velazquez, MD

Operational Contact: David Hufner, Assistant Director, Clinical Operations

Hepatology/GI

Director: Andrew J. Muir, MD

Infectious Diseases

Director: Susanna Naggie, MD

Pulmonary

Director: Scott Palmer, MD, MHS

Outcomes, Health Economics and Quality of Life

Co-Directors: Adrian Hernandez, MD; Elizabeth R. DeLong, PhD; Daniel B. Mark, MD, MPH

Center for Clinical and Genetic Economics

Director: Kevin A. Schulman, MD, MBA

Deputy Director: Lesley Curtis, PhD

Imaging

Director: Pamela Douglas, MD

Director of Operations: Pam Buckholz



Advanced Biomarkers

Director: Kristin Newby, MD

Integrated Clinical Events and Safety Surveillance

Co-Directors: Renato Lopes, MD and Karen Alexander, MD

4. Faculty Advisory Board

Composition: *(List of membership, frequency of Board meetings, term of members, define how membership will be chosen or appointed)*

The DCRI leadership structure includes the Director, Executive Leadership, Faculty Leadership and Operational Leadership.

The DCRI Executive team functions as the Faculty Advisory Board for the DCRI CRU. The Executive team is comprised of Therapeutic Area faculty leaders, Key Research Program faculty leaders and operational leaders. In its role, the Executive team is responsible for overseeing the academic, scientific, financial, strategic, and operational performance of clinical research efforts within the DCRI CRU.

The Executive team meets twice monthly. The Executive team members are appointed DCRI faculty and they are expected to serve for the duration of their executive role.

Director: Eric D. Peterson, MD, MPH

Executive Leadership: John H. Alexander, MD, MHS (DCRI Faculty Associate Director, DCRI Director- Cardiovascular Research, DCRI Assistant Director- Cardiovascular Industry Trials); Daniel K. Benjamin, MD, PhD, MPH (DCRI Faculty Associate Director); Lisa Berdan (Director Global Outcomes Commercial Mega-trials); Adrian F. Hernandez, MD (DCRI Faculty Associate Director and Co-Director Outcomes Research); Kristen O'Berry (Director, Academic Affairs); Kevin Schulman, MD, MBA (DCRI Faculty Associate Director and Director CCGE); Michael W. Sledge (Chief Financial Officer); Nicole Hedrick (Chief Human Resources Officer); Michael Pencina, PhD (DCRI Faculty Associate Director, Bioinformatics and Biostatistics).

Function: *(Please define how studies will be evaluated and how selection decisions will be made.)*

The DCRI research portfolio spans several therapeutic areas, each led by a therapeutic area faculty leader as listed in item # 3 above. The faculty leaders are responsible for overseeing the academic, scientific, financial, strategic, and operational performance of clinical research efforts within their area. They serve as expert resources and provide guidance and direction to faculty members in their area and to DCRI staff. They have dual accountability to their Department Chair/Division Chief and to the DCRI Director.

Therapeutic Area faculty leaders responsibilities include, but are not limited to (excerpt from the DCRI Faculty Handbook):

- Review all new project opportunities within their therapeutic area in terms of academic



and scientific merit and make decisions in conjunction with individual faculty members regarding which opportunities are desirable to pursue.

- Identify priority areas of research within the therapeutic area and communicate this information to the Business Development and Operations staff.
- Coordinate efforts with Business Development and Operations staff to assess the operational and financial implications of all new project opportunities and make go/no go decisions.
- Review and provide scientific and operational input into protocols for new projects within the therapeutic area.
- Provide direction and input in the development of operational plans for new project opportunities including the services the DCRI will provide, potential collaborators at other institutions, services to be outsourced, etc.
- Ensure that proposals for new project opportunities reflect an appropriate translation of the clinical question to be answered into an operational plan and budget that is feasible from the perspective of both the coordinating center and the investigative site and is feasible in terms of available funding.
- Assure that faculty within the therapeutic area understand the regulatory, operational, and financial implications of their proposed study designs and any proposed collaborative arrangements with investigators at other institutions.
- Serve as a resource to PIs, Business Development staff, and Operations staff in the development of budgets for new project opportunities and in negotiations with sponsors.
- Make recommendations to the DCRI Director regarding the development of annual revenue targets and the faculty and operational resources required to support the therapeutic area.
- Monitor the financial performance of all clinical research projects within the therapeutic area to ensure that they meet budget targets.
- Support the operational health of the DCRI by balancing scientific/academic goals with realistic operational capabilities; in this context, participate in joint decision-making with DCRI operational leaders.

5. CRU Governance and Financial Plan:

The DCRI CRU Director reports to the DCRI Director.

All DCRI studies are backstopped by a pool of central DCRI reserves.

Sources of funding for the DCRI projects: Commercial pharmaceutical & biotech companies, Foundations, federal government.

In general, for DCRI projects the margins/deficits are aggregated to central reserve funds.

DTMI projects are backstopped by DTMI funds.

Sources of funding for the DTMI community projects: Commercial pharmaceutical & biotech



Companies, Foundations, federal government.

In general, for DTMI community projects the margins/deficits are aggregated to DTMI central funds.

6. CRU Stakeholders:

Please list the CRU Stakeholders, which could include departments, centers, institutes, CSUs and schools.

The DCRI CRU stakeholders include but are not limited to:

- Departments, e.g. Pediatrics, Medicine, Anesthesiology, Surgery.
- Divisions, e.g. Cardiology, Gastroenterology, Infectious Diseases, Rheumatology.
- Other Centers and Institutes, e.g. Center for Aging, Center for Human Genome Variation.
- Other CRUs and various research administrative offices such as DOCR, IRB, OCRC, ORA, RIO, Office of Export Control and OSP.

Other stakeholders include the NIH and other federal agencies, industry sponsors, foundations, and academic partners with whom DCRI study teams collaborate.

7. Communication Plan:

Please describe how information about the CRU will be actively communicated to CRU faculty and staff.

DCRI CRU information will be communicated to DCRI faculty and staff via the DCRI intranet, e-mail, and meetings. DCRI CRU will send out research information notifications regarding changes in regulatory requirements, institutional standards and DCRI policies and SOPs whenever such changes occur.