Clinical Research Unit Charter

Duke University School of Medicine

Duke Office of Clinical Research

Name of CRU: Duke Clinical Research Unit

Date Form Completed: July 26, 2016

CRU Director Signature: Michael Cohen-Wolkowiez, M.D., Ph.D. Digitally signed by Michael Cohen-Wolkowiez, M.D., Ph.D. Date: 2016.08.03 13:10:31 -04'00'

Unit Head Signature: _____

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1. **Scope of Research within the CRU:**
   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 Duke Clinical Research Unit (DCRU) will support, oversee, and serve as the organizational home for all clinical research conducted within the DCRU. The DCRU CRU will be responsible for the scientific integrity, quality, academic productivity, regulatory compliance, and financial solvency of all clinical research conducted under the DCRU CRU oversight.

The organizational focus of the DCRU CRU is site-based research; however, laboratory activities and storage, chart review for study purposes, DCRU volunteer database activities, and oversight of database projects will be included in the CRU.

In addition, the DCRU provides research services to Duke University Faculty for studies conducted under their Departmental CRUs. For these studies the DCRU CRU provides no CRU oversight. Research procedures completed by DCRU staff performed in these studies will be performed following DCRU standard operating procedures (SOP's).

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2. **Key Personnel:**

Faculty Director: Michael Cohen-Wolkowiez, MD PhD

Operational Director: Donna Hamel, RCP

CRU Research Practice Manager: Margaret Stewart, RN, BA

CRU Financial Practice Manager: Lucian Cappoli, MBA

Other: N/A

3. **Define Clusters and Leadership within Clusters:**

The DCRI/DCRU structure is such that the Director of Clinical Trials Operations holds the primary responsibility for the operations of the unit. Therefore the Research Practice Manager and the Financial Practice Manager report directly to the Director of Clinical Trials Operations. The Director of Clinical Trials Operations and the Faculty Director work as a partnership in the overall management of the DCRU. The Faculty and Operations Directors meet regularly to discuss, plan, and oversee the functions of the unit to assure optimal conduct and quality is achieved. The Financial Practice Manager meets regularly with DCRI financial team as well as the DCRU Faculty and Operations Director regarding financial information.

4. **Faculty Advisory Board**

Composition: (list of membership, frequency of board meetings, term of members, define how membership will be chosen or appointed)

The DCRU Leadership Team functions as the Faculty Advisory Board for the DCRU CRU. In its role, the Faculty Advisory Board is responsible for overseeing the academic, scientific, financial, strategic, and operational performance of the clinical research efforts within the DCRU CRU.

Members of Leadership Team:

Faculty Director, Associate Faculty Director, Medical Director, and Director of Operations.

Function: *Define how studies will be evaluated and how selection decisions will be made.*

Potential new studies will be reviewed by the DCRU Leadership Team, the Finance Practice Manager, and any identified stakeholders. This review includes a formalized meeting, discussion of protocol or synopsis, scientific merit assessment, feasibility of conduct both financial and operational, and a deadline for determination. If a decision is made to move forward, a proposal will be drafted and shared with the sponsor.

5. **CRU Governance and Financial Plan:**

Describe to whom the CRU reports and is ultimately accountable, and which organization(s) provide the backstop for the CRU. If more than one organization provides the backstop for the CRU, ensure that a memorandum of understanding (MOU) has been drafted. Describe sources of funding for CRU and method of allocation of CRU fixed costs to studies. What happens to margins and deficits?

The DCRU is accountable to DCRI. The DCRI provides the backstop for the DCRU CRU. Sources of funding for the DCRU projects include: commercial, government, foundation investigator initiated and internally-funded. Internally-funded projects are supported by

margins from related industry studies (e.g. writing additional manuscripts beyond those covered in the study scope with the sponsor). If there is no related margin or not enough margin to cover the work, the DCRI provides funds. In all cases (whether there is available margin or there is the need to utilize DCRI funds), approval is needed from the Senior Director, Clinical Trials Domain, The DCRI Chief Finance Officer, and from the DCRU Faculty Director. At which point the DCRU Finance Practice Manager assess and determines available funds and assures there is a fund code to track the expenditures.

For projects conducted under the DCRU CRU, the margins/deficits are reconciled by DCRI finance group (note: the DCRI finance group also performs some other FPM duties). The DCRU records any study residuals in what is known as a close-out fund code (every DCRI business unit has its own close-out fund code). Ultimately, any remaining residuals across the DCRI are managed by the DCRI Director.

The DCRU CRU does not have a single hub code but rather cost centers are established to account for functions (e.g. nurse practitioners, project leaders, study coordinators, etc.). Staff working on projects time track allowable and allocable effort to the applicable study. Since the cost centers are functionally based, standard cost rates are established for time tracking. Also, non-labor expenses that cannot be charged to a study are accounted for in the applicable cost center. Study margins cover residual cost center expenses that cannot be charged to projects. These residual expenses are analogous to hub operational expenses. As needed, the DCRI backstops these expenses.

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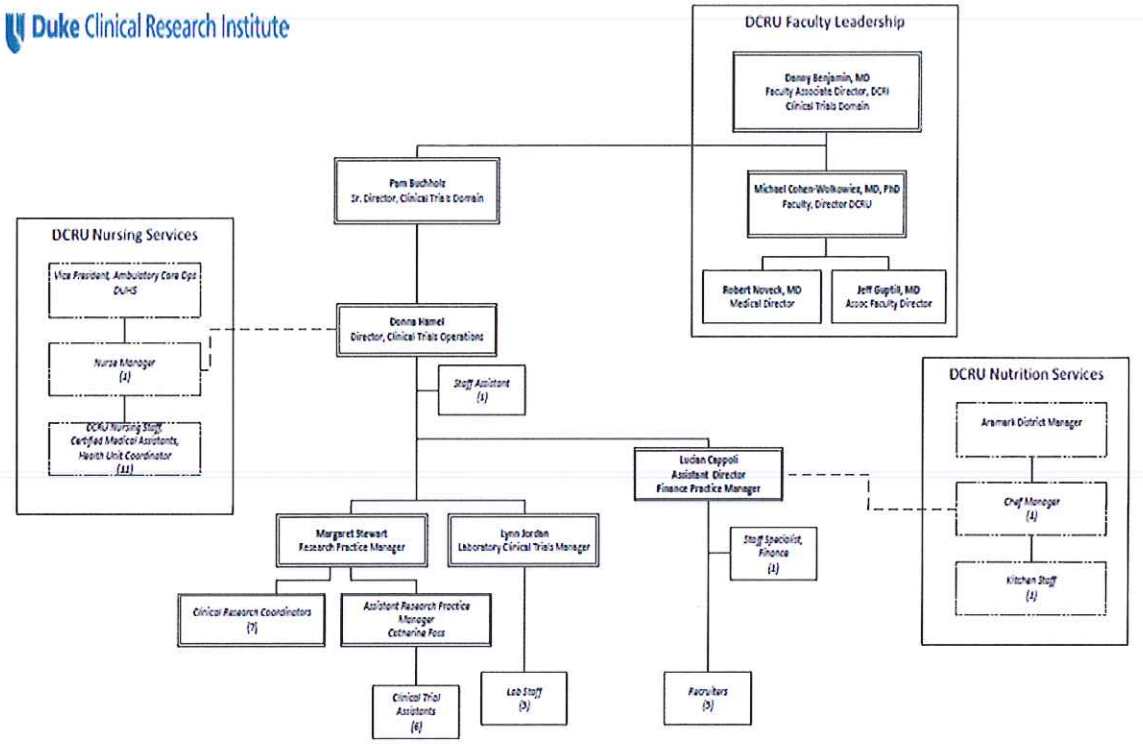
6. **CRU Stakeholders:**
List the CRU Stakeholders, which could include departments, centers, institutes, CSUs and schools.

The DCRU CRU stakeholders include but are not limited to:
- Departments and Divisions within Duke School of Medicine which require research support from the DCRU.
- Other CRU's and various research administrative offices such as DOCR, IRB, OCRC, ORA, and RIO.
- NIH and other Federal agencies, Industry sponsors, Foundations, and other academic partners with whom DCRU study teams collaborate.

7. **Communication Plan:**
Describe how information about the CRU will be actively communicated to CRU faculty and staff.

The DCRU CRU information is communicated to DCRU faculty and staff via the DCRI intranet, email, and meetings. DCRU CRU will send out research information notifications regarding changes in regulatory requirements, institutional standards and DCRI/DCRU/SOM policies and SOPs whenever such changes occur.

Organizational Chart:



June 2016

Duke Clinical Research Unit