Clinical Research Unit Charter

Name of CRU: Heart Center Clinical Research Unit

Date Form Completed: April 2016

CRU Director Signature: [Signature]

Unit Head Signature: [Signature]

1. **Scope of Research within the CRU:**

The Heart Center (HC) CRU will support, oversee and serve as the organizational home for all clinical research conducted within the Duke Heart Center. This will include all clinical research that has IRB oversight at Duke through the Division of Cardiology. The HC CRU will be responsible for the scientific integrity, quality, academic productivity, regulatory compliance, and financial solvency of all clinical research conducted in the Heart Center.

The organizational focus of the CRU will be on site-based research; however, all core-laboratory, chart review, and database analysis research projects will also be included in the CRU. Different types of clinical research will require and be supported with different levels of infrastructure support.

The resources required for the coordination of multicenter clinical research is beyond the scope of the Heart Center CRU infrastructure. These projects will not be included in the Heart Center CRU.

Organization of site based clinical research around the Heart Center is logical as the research portfolios share common disease and patient populations and such organization allows effective integration with clinical enterprise.

2. **Key Personnel:**

Medical Director: W. Schuyler Jones, MD
CRU Research Practice Manager: Jennifer Hamill, RN, MSN
CRU Financial Practice Manager: Jennifer Langefeld

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

The Heart Center CRU will be organized into Research Clusters aligned with the clinical organization of the Heart Center. All Site-Based Research will be conducted within one of these Clusters. Each Cluster will have a Medical Director or Faculty Director and a Lead Coordinator. The CRU Director and Heart Center Director will appoint Cluster Medical Directors. The Cluster Medical/Faculty Director in consultation with Heart Center Research Practice Manager will choose lead Coordinators.
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<table>
<thead>
<tr>
<th>Research Cluster</th>
<th>Medical/Faculty Director</th>
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<tbody>
<tr>
<td>Catheterization Cluster</td>
<td>Manesh Patel, MD</td>
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<tr>
<td>Electrophysiology Cluster</td>
<td>Brett Atwater, MD</td>
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<tr>
<td>Heart Failure Cluster</td>
<td>Chetan Patel, MD</td>
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<tr>
<td>Imaging Cluster</td>
<td>Zainab Samad, MD</td>
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<tr>
<td>Lumerton Cluster</td>
<td>Melvin Echols, MD</td>
</tr>
<tr>
<td>Primary and Acute Cardiology Cluster</td>
<td>L. Kristin Newby, MD</td>
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</tbody>
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4. Faculty Advisory Board

Composition: The Heart Center CRU Faculty Advisory Board (FAB) will include the Director of the Heart Center CRU, the Director of the Heart Center, the Division Chief of Cardiology, and the Medical Directors the Heart Center CRU Research Clusters.

Function: Heart Center FAB meetings will be held at least twice a year. In addition the FAB members, the CRU Managers for Research and Financial Practices, the Cardiology Business Manager and each Cluster’s Lead Coordinator will be invited to attend. The Heart Center FAB will review the scientific and financial portfolios of the overall CRU and each Cluster. The FAB will provide direction to the CRU and serve a consultory function to the Heart Center CRU regarding infrastructure priorities, research priorities, use of central funds, overhead structure and other relevant issue.

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 Heart Center CRU will report to the Heart Center Leadership specifically to:

- The Chief of Cardiology
- Division Administrator of Cardiology

The Duke Heart Center CRU will sit within the School of Medicine but outside of the Department of Medicine. It will be administratively housed within the “Heart Center” within the School of Medicine. The Heart Center and Heart Center Leadership will have a dual reporting relationship to the health system, which is providing the financial backstop and to the School of Medicine, which is responsible for overseeing the academic productivity of the CRU.

Ultimately, the Heart Center will provide the financial backstop for the infrastructure activities of the Heart Center CRU, however the Heart Center CRU will be responsible for managing a balanced budget and each cluster will responsible for managing their own portfolio bottom line to a financially neutral or positive position. Funding for
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the Heart Center CRU will come from a variety of sources including from SOM indirect recovery, Duke University Health System support and Heart Center CRU overhead allocation to each CRU project. The Heart Center CRU overhead allocation will be determined annually by the CRU.

Research Clusters will be responsible for project evaluation and selection. Each Cluster Medical Director and Lead Coordinator will be responsible for developing a process to choose research projects conducted through their cluster. All new research projects will undergo review prior to acceptance into the Heart Center CRU. The documentation of this review process will occur within the eIRB system. The Cluster Faculty Lead or HC CRU Medical Director will determine whether the Statistical Review Program is needed. The Medical Director from each cluster will review a new project and document their findings with the HC CRU Scientific and Feasibility Review Checklist. Acceptance of a project into a cluster will be documented by the checklist and “no major concerns” designation in the eIRB. Projects will then undergo Departmental Review. Only projects that receive the distinction of “no major concerns” will be moved ahead to final review by the CRU Medical Director.

All contracts and budgets will undergo review by the Central HC CRU Finance team. Final approval will not be released until the study team has completed the HC CRU PI or Cluster Agreement. The HC PI or Cluster Agreement will detail enrollment goals and also identify a funding source sufficient to cover the costs of the project including coverage for unexpected losses. Margins from closed projects, both positive and negative, will remain within the Cluster and Cluster General Research Account (GRA). Cluster GRAs are only to be used for general operating expenses and to cover negative margins from closing studies if funds are available. If GRA is negative at study closure, the PI or Cluster agreement would make the PI or Cluster responsible for recovering the negative balance.

The Heart Center CRU will be responsible for assisting the clusters in achieving and maintaining a portfolio of research that has fiscal solvency, institutional and regulatory compliance and scientific relevancy. Each Research cluster will be responsible for complying with agreed upon CRU compliance and financial policies, for the conduct of scientifically important research, and maintain a financially breakeven or positive balance.

On an annual and ad hoc basis, the Heart Center CRU will meet with the leadership of each Cluster to review the financial status and scientific relevancy of the cluster portfolio as well as review study conduct or personnel issues, study closures, or audits. Should a cluster have a significant financial deficit, have regulatory, compliance or quality issues, have a research portfolio of limited scientific value, or have other issues that warrant concern, a corrective action plan will be developed.
6. **CRU Stakeholders:**

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

   Our most important stakeholders are our patients, both the DUHS patients who have the opportunity to participate in Heart Center CRU projects and current and future patients with cardiovascular disease who benefit from the information obtained from the Heart Center CRU projects.

   Other key stakeholders include the Duke Heart Center and the Duke University School of Medicine including the faculty in the Divisions of Cardiology.

   In addition, the physicians and staff of Duke Hospital, Durham Regional Hospital, Duke Raleigh Hospital, Duke Affiliate Hospitals, the Duke Outreach Clinics and the Duke Clinical Research Institute are all Heart Center CRU Stakeholders.

   Additional potential stakeholders include other Divisions and Departments within Duke Medical Center with whom the Heart Center researchers may collaborate, and the various research administrative offices at Duke-IRB, ORA, etc. Other stakeholders include the NIH, industry sponsors, small business partners and other academic and industry collaborators within and outside of Duke.

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7. **Communication Plan:**

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

   Timely, effective and transparent communication is critical to the success of the Heart Center CRU. Thus, the Heart Center CRU will maintain a service standard that all requests for information or assistance from stakeholders will be acknowledged the same day and serviced as soon as possible. Heart Center CRU staff will make every effort to ensure that all stakeholders receive regular communication regarding the operation of the Heart Center CRU.

   All stakeholders will have access to the Heart Center CRU intranet site which will include comprehensive information about CRU membership, organization, processes and procedures, projects, and financial and operational updates.

   The Heart Center CRU FAB will meet at least twice a year as described above. The Heart Center CRU Administrative meetings inclusive of the RPM, ARPM, FPM, Medical Director and Business Manager for Cardiology, will occur weekly to discuss both successes and points of escalation. The RPM and ARPM will meet weekly to discuss administrative issues and the quality assurance initiatives. The Cluster lead coordinators will meet twice a month to share knowledge and updates across clusters. The Leads of each cluster will meet with their research staff at least once a month to communicate ongoing initiative and address any concerns. The FPM and finance team will meet with Cluster leads no less than every other month to discuss financial reports. Open forums and ad hoc meetings will be scheduled as necessary by either email, telephone or face to face meetings.