Clinical Research Unit Charter

Duke University School of Medicine

DUKE UNIVERSITY SCHOOL OF MEDICINE

Name of CRU: **Dermatology/Pathology**

Date: **01/24/2013**

CRU Director Signature: _____

1. Scope of Research within the CRU:

The scope of the Dermatology/Pathology Clinical Research Unit (CRU) includes all clinical research studies involving human subjects at Duke University Medical Center within the Departments of Dermatology and Pathology. Further, the CRU will provide oversight for clinical research in which Duke Medicine is the investigative site for the research and a Duke Medicine faculty member is responsible for direct interventions, observations, surveys or interactions with Duke patients and research subjects, the use of biologic specimens from Duke patients and research subjects, and access to confidential, private information from Duke patients and research subjects. This oversight will also include any projects for which a CRU faculty member is PI of the Duke site as a coordinating center.

2. Key Personnel:

Director- Russell P. Hall, III MD
CRU Manager – Research Practice- Deborah Hannah
CRU Manager – Financial Practice -Virginia King-Barker

3. Define Clusters & Leadership within Clusters;

Department of Pathology will be a separate cluster. Sarah Bean, MD will serve and the Medical Director of that cluster.

4. Faculty Advisory Board

Composition:

CRU Medical Director:
Russell P. Hall, MD

Pathology Cluster Medical Director:
Sarah Bean, MD

Faculty Advisors:
John Murray, MD

Elise Olsen, MD
George Cianciolo, PhD

Financial Practice Manager:
Virginia King-Barker

Research Practice Manager:
Deborah Hannah

The faculty advisors will be appointed for a two year term and will be eligible for reappointment. Appointment to faculty advisor is based on the faculty member having experience in clinical research as PI, having current all required IRB and institutional training requirements and a full time appointment in the Department of Dermatology or Pathology.

Meetings will be held on an ad hoc basis and consist of "key personnel" in the charter.

Function:

The responsibilities of the CRU leadership consist of the following:

- Ensure that all protocols and CRU members engaged in clinical research meet the institutional standards including but not limited to compliance in the conduct of research, management of research records, personnel, and financial reporting as designed by the Duke Office of Clinical Research
- Facilitate the education of all faculty, staff and residents regarding Duke University rules, regulations and procedures for the conduct of human subjects research
- Evaluate the scientific merit of each proposal
- Evaluate the feasibility of all clinical research protocols regarding administrative and clinical support needs from physicians, nurse coordinators and clinical research staff
- Evaluate proposed budgets for fiscal solvency
- Review the progress and compliance with all appropriate regulations of ongoing clinical research protocols
- Serve as a resource for faculty, staff and trainees conducting clinical research
- Provide a forum to discuss specific questions and challenges related to the conduct of clinical research in the Departments of Dermatology and Pathology

The process for how studies are evaluated is as follows:

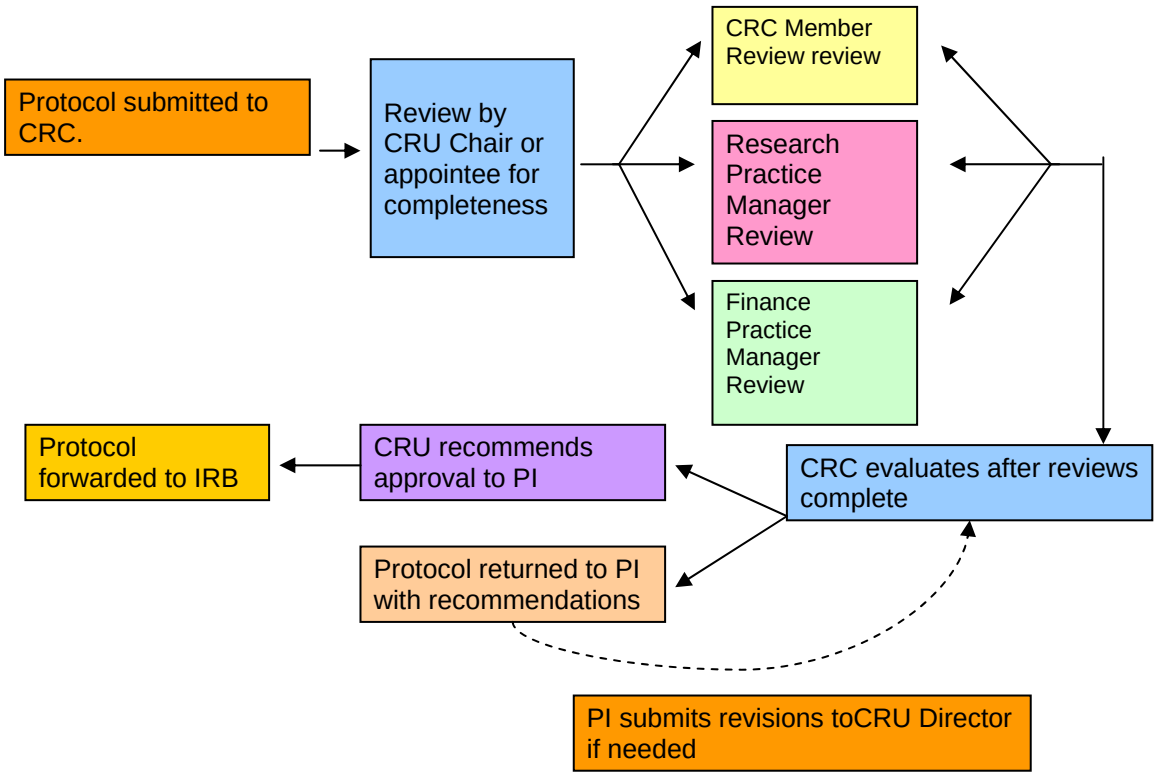
1. Principal Investigator submits new proposal in eIRB and it is routed to the CRU for acceptance.

2. Once accepted by the CRU, Clinical Research Committee Chair or appointee reviews submission for completeness and then distributes to Clinical Research Committee member(s) for review.

3. The following reviews then occur simultaneously:
   a. CRC Member or CRU Director reviews for merit and feasibility.
   b. Research Practice Manager reviews the protocol for feasibility and support needs
   c. Financial Practice Manager performs a budget review
   d. Ad hoc reviews may be obtained as dictated by the proposa l(e.g. statistical review, outside expert review).

4. Clinical Research Committee members or designee will make one of the following recommendations to the Principal Investigator:
   a.
   b. Recommend submission to IRB should proceed with no changes
   c. Recommend revisions of either the protocol or budget to the Principal Investigator before being forwarded to the IRB
   d. Deny the proposal request

Dermatology CRU evaluation of proposals process
*note- communication by electronic means



5. CRU Governance and Financial Plan:

The Dermatology/Pathology CRU reports to the CRU Leadership in the DOCR

Memorandums of understanding (MOUs) will be developed as needed for Departments that utilize the Dermatology CRU services.

The CRU will require each principal investigator to backstop their individual research operations with discretionary funds.

The cost of the centralCRU staff will be funded by a combination of the following at the discretion of the Chairs of Pathology or Dermatology:

- Chair's Office,
- Sharing of indirect cost funds that are returned to the Departments and,
- Allocation of funds from individual clinical trials (see Tiers below),
- Percentage of margin on closed clinical trials (refer to margins and deficits below).

Clinical research projects in the CRU may include an administrative allocation that will be retained from each project as defined by the following:

Tier 1 Sponsor initiated or PI Initiated clinical research project with a clinical trial agreement (CTA), budget/billing grid and subjects sign a consent form.

Tier 2 PI-initiated clinical research project with no CTA, with budget/billing grid and subjects sign a consent form

Tier 3 PI-initiated clinical research project with no CTA, no budget/billing grid and subjects sign a consent form (i.e. databases, questionnaires, blood/tissue samples)

Tier 4 PI- initiated clinical research project with no CTA, no budget/billing grid, and subjects do not sign a consent form (i.e. retrospective reviews)

Tier 5 Clinical research project supported by a grant (e.g. NIH, NCI, FDA)

NOTE: The fees are due in full upon submission of the clinical research project to the Dermatology SBR or when the fund code is assigned. Fees are subject to change.

A portion of margin will be transferred to the CRU Hub upon IRB closeout of the project. Deficits will be managed by discretionary funds of the principal investigator and will be reviewed on case by case basis to ensure solvency of investigators research operations.

6. CRU Stakeholders:

Patients that participate in CRU studies; investigative teams that conduct this research and all Duke Medicine entities they interface with, including, but not limited to, all clinical departments in the School of Medicine, ,Clinical Support Units (CSUs), Centers and Institutes, Durham Regional Hospital, Duke Health Raleigh, the Duke Clinical Enterprise and hospital, Durham VA Medical Center, Department of Veterans Affairs, the NIH, all industry sponsors and foundations, all trainees at Duke, all other academic organizations including the DCRI and finally the offices of DOCR, IRB, OCRC, ORA, and OSP. External stakeholders would include the sponsoring organizations, as well as all the other academic institutions in which our investigative teams collaborate.

7. Communication Plan:

The CRU Leadership team will hold open forum meetings with the clinical research community of the Departments of Dermatology and Pathology. The DOCR intranet site will be updated to include information about the Dermatology/Pathology CRU . The CRU community will be notified of changes to the website via email. CRU leadership will schedule one-on-one meetings with investigators and investigative teams as necessary. The CRU Research Practice Manager and CRU Financial Practice Manager will conduct monthly meetings with the research staff in the CRU. The CRU Advisory Board will meet on an ad hoc basis.