Clinical Research Unit Charter
Duke University School of Medicine

Name of CRU: Ophthalmology

Date: March 4, 2013

CRU Director Signature: 

Unit Head Signature: 

1. Scope of Research within the CRU:
The Ophthalmology Clinical Research Unit (CRU) Group at the Duke Eye Center will oversee the conduct of all clinical research (i.e., any research requiring human subject approval) by faculty in the Department of Ophthalmology. Seven clinical divisions comprise the ophthalmology research community overseen by this CRU: cornea, glaucoma, retina, neuro-ophthalmology, oculoplastics, pediatric ophthalmology and comprehensive ophthalmology.

2. Key Personnel:
   Director: David K. Wallace, MD, MPH
   CRU Manager – Research Practices: Ana M. Garcia-Turner, MSHS
   CRU Manager – Financial Practices: TBD

3. Define Clusters & Leadership within Clusters;
   This CRU group functions as a single entity with six clusters representing seven clinical divisions (neuro-ophthalmology and comprehensive are combined). Please see last page for organizational chart.

4. Faculty Advisory Board
   Members:
   **Anthony Kuo, MD – Cornea
   Kelly Muir, MD – Glaucoma
   Mays El-Dairi, MD – Neuro-Ophthalmology / Comprehensive
   Scott Cousins, MD – Vice-Chair for Research - Retina
   Glenn Jaffe, MD – Retina
   **Michael Richard, MD – Oculo-Plastics
   David Wallace, MD., MPH – CRU Director - Pediatric Ophthalmology
   Sandra Stinnett, PhD – Statistician

   Alternate members and Departmental IRB reviewers:
   Edward Buckley, MD – Neuro-Ophthalmology
   **Stuart McKinnon, MD, PhD – Glaucoma
   **Sharon Freedman, MD – Pediatric Ophthalmology
   **Prithu Mettu, MD - Retina
   **Eleanor Lad, MD, PhD - Retina

   ** Department of Ophthalmology IRB representative
Function:
The Faculty Advisory Board will assist the CRU leadership team (Director, Practices Manager and Financial Manager) on the conduct and oversight of clinical research within the Department of Ophthalmology, including but not limited to the following:

- Advise on implementation of School of Medicine policies;
- Communicate to the CRU leadership team emerging issues of importance for the faculty and assist in developing departmental-specific policies to address them;
- Provide feedback, as needed, to study teams and IRB reviewers prior to project routing to the Duke Institutional Review Board (IRB);
- Communicate clinical research information, issues and updated policies to the faculty members of their respective services; and,
- Assist in the development of educational and mentoring resources for faculty members and trainees.

The CRU Faculty Advisory Board will meet as needed. Members will hold the position for a 3-year term. All members will be appointed by their respective service chiefs or the CRU Director. In addition, the reviewers, who will also serve as alternate members of the Faculty Advisory Board, will be appointed by the CRU Director and service chiefs.

The policy for reviewing clinical research proposals will be reviewed and updated annually, at a minimum. For each new proposed study, the principal investigator (PI), with assistance from their clinical research staff, will submit the proposed project via the Duke e-IRB. Each project submission will be reviewed by one Departmental IRB reviewer, as well as the CRU Practices and Financial Managers for the following criteria:

- Scientific merit - Is the study design appropriate?
- Consent form (if available and applicable) - Does the consent form adequately communicate risks and benefits of the proposed research?
- Resource requirements - Are clinical research coordinators, statisticians and clinical research facilities available?
- Financial feasibility - What is the potential financial exposure for the department (high or low)? If high, is the funding source adequate to meet costs?
- Enrollment potential - Can the investigator recruit an adequate number of subjects? Are there active (or upcoming) competing projects?
- Priority and impact - Is this project important to the investigator? Will the results advance the practice of ophthalmology?

For all projects deemed “Approve”, the clinical research project will be routed to the Duke Institutional Review Board.

For any project deemed to have serious deficiencies in one of the major review criteria, an initial designation of “Modifications” or “Disapprove” will be made. The study staff and PI will review and implement the requested changes prior to final review/approval.

If desired, the PI will be given the opportunity to meet with the CRU Director and
Research Practices Manager to discuss the requested changes/review. If following a meeting with the CRU Director, IRB reviewer and RPM the proposed project cannot be approved for IRB submission, the proposal will be assigned to the next convened meeting of the Faculty Advisory Board for discussion. The final disposition of the proposal will be made by the group.

The study information is tracked in a database maintained within the Duke Eye Center.

5. CRU Governance and Financial Plan:
The CRU Director reports to the Vice-Chair for Research, Dr. Scott Cousins, and to the Chairman, Dr. David Epstein. For most administrative decisions, the CRU Faculty Advisory Board provides recommendations to the CRU Director.

CRU funding:
The Department of Ophthalmology will provide salary support for the CRU Director, Research Practices Manager and the Finance Practices Manager. In addition, the department may provide funds (determined annually) to support administrative costs for certain research projects considered to be high priority by the chairman and the vice chair for research.

A process will be developed to determine the departmental administrative costs and other costs incurred by the CRU. The Department of Ophthalmology’s CRU will generate funds to support administrative costs by several strategies:

- Administrative startup and close-out fees will be built into the budget of all funded trials, and will be collected when a fund code is assigned. Fees will be adjusted according to the type and complexity of the study.
- Upon close-out of any study with transfer of residual funds to discretionary accounts, a mandatory "tax" on the residuals will assessed.
- Additional strategies to generate funds will be developed.

These strategies will be reviewed, at a minimum, annually, and any changes in fees and taxes will be communicated to faculty by email, through the Faculty Advisory Board and at a faculty meeting in the Fall of each academic year.
6. CRU Stakeholders:
   - Duke Eye Center faculty, administration, and study coordinators
   - Duke Eye Center patients
   - SOM Departments, Duke Health System

7. Communication Plan:
   Because of the relatively small size of the clinical research faculty within the Department of Ophthalmology, CRU issues and action will be reported to all faculty members, clinical research staff and administrators via e-mail or at faculty/staff meetings.