Clinical Research Unit Charter
Duke University School of Medicine

Name of CRU: Ophthalmology

Date: June 27, 2016

CRU Director Signature: 

Unit Head Signature: 

1. Scope of Research within the CRU:
The Ophthalmology Clinical Research Unit (CRU) 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
   Research Practice Manager (RPM): Ana M. Garcia-Turner, MSHS
   Financial Practice Manager (FPM): TBD

3. Define Clusters & Leadership within Clusters:
   This CRU 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
   Maya El-Dairi, MD – Neuro-Ophthalmology / Comprehensive
   Scott Cousins, MD – Vice-Chair for Research - Retina
   Glenn Jaffe, MD – Retina
   David Wallace, MD, MPH – CRU Director - Pediatric Ophthalmology
   Sandra Stinnett, PhD – Statistician

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

   ** Department of Ophthalmology IRB representative

Function:

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The Faculty Advisory Board will assist the CRU leadership (Director, RPM and FPM) on the conduct and oversight of human 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 at least 3 years. All members, and alternate members, will be appointed by their respective service chiefs and/or the CRU Director.

For each new proposed study, the principal investigator (PI), with assistance from 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 Research and Financial Practice 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?

All “Approved” projects 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/revision.

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 a 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. Policies will be reviewed as needed.

5. **CRU Governance and Financial Plan:**
The CRU Director reports to the Vice-Chair for Research and to the Chairman. 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.

The Department of Ophthalmology’s CRU will generate funds to support administrative costs by several strategies:

- Administrative startup and close-out fees are built into the budget of all funded trials, and are collected when a fund code is assigned. Fees are 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 is assessed.
6. **CRU Stakeholders:**
   - Duke Eye Center faculty, administration, and study coordinators
   - Duke Eye Center patients
   - SOM Departments, Duke Health System
   - DOCR, IRB, OCRC, ORA, SOM Finance, DOARC
   - Sponsors and government agencies

7. **Communication Plan:**
   CRU issues, such as changes in start-ups, and actions, such as institutional policy changes, will be reported to all faculty members, clinical research staff and administrators via e-mail and/or at faculty/staff meetings.
4. (Continued) Organization Chart:

Organizational Chart

Edward Buckley, MD
Chairman

Scott Cousins, MD
Vice-Chair of Research

Adrienne Lloyd, Chief Administrator

David Wallace, MD, MPH
CRU Director

CRU Faculty Advisory Board:
Scott Cousins, MD
Mays El-Dairi, MD
Glenn Jaffe, MD
Anthony Kuo, MD
Kelly Muir, MD, MPH
David Wallace, MD, MPH

CRU Alternates Members:
Edward Buckley, MD
Stuart McKinnon, MD, PhD
Sharon Freedman, MD
Prithu Mettu, MD
Sandra Stinnett, PhD - statistician

TBD
CRU Financial Practice Manager

Ana Garcia-Turner
CRU Research Practice Manager

Clinical Research Coordinators

Investigators

Clusters:
Comprehensive
Cornea
Glaucoma
Neuro-ophthalmology
Oculoplastics
Pediatric
Retina

IRB Reviewers:
Sharon Freedman, MD—pediatrics
Stuart McKinnon, MD, PhD—glaucoma
Anthony Kuo, MD—cornea
Priyatham Mettu, MD—retina
Michael Allingham, MD, PhD—retina
Jullia Rosdahl, MD, PhD—glaucoma