Site-Based Research Charter
Duke University School of Medicine

Name of SBR: Ophthalmology

Date: January 1, 2010

SBR Director Signature: [Signature]

Unit Head Signature: [Signature]

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

2. **Key Personnel:**
   Director: Scott W. Cousins, M.D.
   SBR Manager - Research Practices: Ana M. Garcia-Turner
   SBR Manager - Financial Practices: to be named

3. **Define Clusters & Leadership within Clusters:**
   This SBR group functions as a single entity with seven clusters representing each clinical service. Please see last page for organizational chart.

4. **Faculty Advisory Board**
   **Members:**
   - Natalie Afshari, M.D. – Cornea
   - Rand Allingham, M.D. – Glaucoma
   - M. Tariq Bhatti, M.D. – Neuro-Ophthalmology
   - Scott Cousins, M.D. – Retina—SBR Director
   - Glenn Jaffe, M.D. – Retina
   - Paul Lee, M.D., J.D. – Glaucoma
   - David Wallace, M.D., MPH – Pediatric Ophthalmology
   - Sandra Stinnett, Ph.D. – Statistician
   **Alternate members and reviewers:**
   - Christopher Boehlke, M.D. – Cornea
   - Edward Buckley, M.D. – Neuro-Ophthalmology
   - Stuart McKinnon, M.D., Ph.D. – Glaucoma
   - Kelly Muir, M.D. – Glaucoma
   - Michael Richard, M.D. – Oculoplastics
   - Tammy Yanovitch, M.D. – Pediatrics

   **Function:**
The Faculty Advisory Board will assist the SBR leadership team (Director, Practices Manager and Financial team) on the conduct and oversight of clinical research within the Department of Ophthalmology, including but not limited to the following:
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- Advise on implementation and respond to School of Medicine policies;
- Communicate to the SBR leadership team emerging issues of importance for the faculty and assist in developing departmental-specific policies to address them;
- Evaluate clinical research proposals and provide feedback to faculty prior to submission 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 and trainees.

The SBR Faculty Advisory Board will meet at a minimum once per quarter with members holding the position for a 3-year term. All members will be appointed by their respective service chiefs or the SBR Director. In addition, the reviewers, who will also serve as alternate members of the Faculty Advisory Board, will be appointed by the SBR Director and service chiefs.

The specific policy for submission of clinical research proposals will be developed and updated annually, at a minimum. In general, any investigator who intends to submit a proposal will be encouraged to meet with the SBR Research Practices Manager and/or the Director prior to submission for assistance. For each new proposed study, the principal investigator (PI), with assistance from their clinical research staff, will submit the proposed project to the SBR for preliminary review and approval. Each project submission will be reviewed by one SBR reviewer, one member of the Faculty Advisory Board, as well as the SBR Practices and Financial Managers for the following criteria:

- Scientific merit - Is the study well designed?
- 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 exceed costs?
- Enrollment potential - Can the investigator recruit adequate 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?

The conclusions of the reviewers will be evaluated by the SBR Director or designee. All members of the Faculty Advisory Board will be given a copy of the review with opportunity for comments.

For all projects deemed "Approve", an email will be sent to the study staff and the clinical research project may be submitted for Institutional Review Board.

For any project deemed to have serious deficiencies in one of the major review criteria, an initial designation of "Revise" or "Disapprove" will be made. An email will be sent to
the study staff and PI informing them that the project may not be submitted to the IRB. If desired, the PI will be given the opportunity to meet with the SBR Director and Research Practices Manager to discuss the review. If following this meeting 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 database maintained within the Duke Eye Center.

5. SBR Governance and Financial Plan:
The SBR Director reports directly to the Chairman, Dr. David Epstein. For most administrative decisions, the SBR Faculty Advisory Board provides recommendations to the SBR Director.

SBR funding:

The Department of Ophthalmology will provide salary support for the SBR Director, Research Practices Manager and the Finance Practices Manager. In addition, the department will 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 SBR. The Department of Ophthalmology’s SBR 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. SBR 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, SBR issues and action will be reported to all faculty members, clinical research staff and administrators via e-mail or at faculty/staff meetings. We are also planning a website where all SBR announcements, meeting minutes, and templates will be posted.