

Site-Based Research Charter

Duke University School of Medicine



Name of SBR: **Surgery**

Date: **June 15, 2009**

SBR Director Signature: _____

Unit Head Signature: _____

1. Scope of Research within the SBR:

Cardiovascular and Thoracic Surgery, Emergency Medicine, Experimental Surgery, General Surgery, Neurosurgery, Oral and Maxillofacial Surgery, Orthopaedic Surgery, Otolaryngology, Pediatric Surgery, Plastic and Reconstructive Surgery, Speech Pathology and Audiology, and Urology

2. Key Personnel:

Director: Jeffrey Lawson, MD, PhD

Associate Director: Paul Kuo, MD

SBR Manager – Research Practices: Sherri Jarvis, RN

Associate SBR Manager – Research Practices: Terry Ainsworth, NP

SBR Manager – Financial Practices: Ti-An Ferrell

Other: Executive Director: Dave Anderson

Regulatory Affairs and Compliance: Tracy Kerby, BSBA, MA

Surgery Finance Manager: Pam Gorham, MBA

3. Define Clusters & Leadership within Clusters:

<u>Cluster</u>	<u>Medical Director</u>	<u>Lead Study Coordinator</u>
Cardiovascular and Thoracic Surgery	James Lowe, MD	Terry Ainsworth
Emergency Medicine	Abhinav Chandra, MD	Debra Freeman
General Surgery	Lee Wilke, MD	Sherri Jarvis
Neurosurgery	John Sampson, MD, PhD	Terry Ainsworth
Orthopaedic Surgery	Michael Bolognesi, MD	Molly Gavigan, RN
Otolaryngology	Walter Lee, MD	Tasha Carmon
Pediatric Surgery	Henry Rice, MD	Terry Ainsworth
Plastic and Reconstructive Surgery	Deltev Erdmann, MD	Terry Ainsworth
Speech Pathology and Audiology	Frank Deruyter, PhD	Jessica House
Surgical Sciences	Bruce Sullenger, PhD	Smita Nair, PhD
Urology	Cary Robertson, MD	Jill Smith

4. Faculty Advisory Board

Composition:

Director: Jeffrey Lawson, MD, PhD

Associate Director: Paul Kuo, MD

SBR Manager – Research Practices: Sherri Jarvis, RN

Associate SBR Manager – Research Practices: Terry Ainsworth, NP

SBR Manager – Financial Practices: Ti-An Ferrell

Executive Director: Dave Anderson

Regulatory Affairs and Compliance: Tracy Kerby, BSBA, MA

Surgery Finance Manager: Pam Gorham, MBA

<u>Cluster</u>	<u>Faculty Advisory Board Member</u>
Cardiovascular and Thoracic Surgery	James Lowe, MD
Emergency Medicine	Abhinav Chandra, MD
General Surgery	Lee Wilke, MD
Neurosurgery	John Sampson, MD, PhD
Orthopaedic Surgery	Michael Bolognesi, MD
Otolaryngology	Walter Lee, MD
Pediatric Surgery	Henry Rice, MD
Plastic and Reconstructive Surgery	Deltev Erdmann, MD
Speech Pathology and Audiology	Frank Deruyter, PhD
Surgical Sciences	Bruce Sullenger, PhD
Urology	Cary Robertson, MD

The Faculty Advisory Board will meet quarterly and consists of the Cluster Medical Directors and Surgery SBR personnel identified as “Key Personnel” in the charter.



Function:

On a quarterly and ad hoc basis, the Faculty Advisory Board will review the financial status of clinical research projects, serious adverse events/deaths, enrollment, personnel issues, study conduct issues (i.e., billing, etc.), study closures and audits.

New clinical research projects will be reviewed by the Cluster (Division Chief, Cluster Medical Director and Cluster Lead Coordinator). The clinical research project will be reviewed for the following:

- Support from Division Chief
- Scientific relevance
- Financial feasibility
- Manpower – i.e., Study Coordinator, Statistician, etc.
- Patient base – Are there competing clinical research projects? Are there sufficient patients available to meet enrollment goal? etc.
- Facilities – Pharmacy, PK room, Radiology, etc.
- Involvement of other departments

Upon recommendation of the Cluster, the clinical research project will be sent to the SBR Director/Designee for final review.

If the SBR Director/Designee recommendation is for “Approval”, an e-mail will be sent and the clinical research project **may** be submitted to the Institutional Review Board (IRB).

If the SBR Director/Designee recommendation is for “Disapproval”, an e-mail will be sent and the clinical research project is “terminated” and **cannot** be submitted to the Institutional Review Board (IRB).

5. **SBR Governance and Financial Plan:**

The Surgery SBR reports to the Chairman of Surgery through the SBR Director and Departmental Administrative structure.

Memorandums of understanding (MOUs) will be developed as needed.

Clinical research projects in the Department of Surgery will include an “administrative fee” (amount to be negotiated annually) based on the following tier definitions:

- Tier I: Sponsor-initiated or PI-initiated clinical research project with a clinical trial agreement (CTA), budget/billing grid and subjects sign a consent form.
- Tier II: PI-initiated clinical research project with no CTA, with budget/billing grid and subjects sign a consent form.
- Tier III: PI-initiated clinical research project with no CTA, no budget/billing grid and subjects sign a consent form (i.e., questionnaires, blood/tissue samples, etc.).
- Tier IV: PI-initiated clinical research project with no CTA, no budget/billing grid and subjects do not sign a consent form (i.e., retrospective reviews, cadaver research, etc.).
- Tier V: Clinical research project supported by a grant (i.e., National Institutes of Health (NIH), National Cancer Institute (NCI), etc.).
- Tier VI: Humanitarian exemption clinical research project.

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

A percent of the aggregate residual at the closeout of the study will be transferred to the Surgery SBR. The percent will be transferred when all clinical research project-related activities have been completed (i.e., Final Report to Institutional Review Board (IRB), verification of expenses and revenue, invoicing, etc.).

6. **SBR Stakeholders:**

Clinical departments, including, but not limited to, Anesthesiology, Oncology, Pediatrics, Pharmacy and Radiology

Clinical Service Units (CSUs), including, but not limited to the Heart Center

Duke Clinical Research Institute (DCRI)

Duke Comprehensive Cancer Center

Duke Translational Medicine Institute (DTMI)

Institute for Genome Sciences and Policy (IGSP)



7. Communication Plan:

The Surgery intranet site will include information about the Surgery SBR. Components of the intranet site include: Announcements, Contacts, Guides, and Policies and Procedures. Open forums and one-on-one meetings with faculty members will be scheduled as necessary. The SBR Managers – Research Practices will conduct periodic meetings with the Study Coordinators in the Surgery SBR. The SBR Faculty Advisory Board will meet on a quarterly basis. Surgery e-News will be utilized as necessary for announcements. Announcements will be posted on the Surgery intranet as well.

4. (Continued) Insert Organization Chart:

Organizational Chart Research Administration

