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:

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:

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

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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: