1. **Scope of Research within the Orthopaedic Surgery SBR:**
The scope of the Orthopaedic Surgery Site based Research (SBR) includes all clinical research and regulatory oversight that is conducted in the Department of Orthopaedic Surgery, including the following Divisions: Foot & Ankle, Hand & Upper Extremity, Joint and Adult Reconstruction, Oncology, Pediatrics, Spine, Sports Medicine, Trauma and General Orthopaedic Surgery. This SBR will provide oversight for clinical research where the investigative site is part of Duke Medicine and our faculty members are responsible for direct interventions, observations, surveys, interactions with Duke patients, use of biologic specimens and access to confidential, private information from Duke patients that involves clinical research.

2. **Orthopaedic Surgery Key Personnel:**
Director: Steven Olson MD
Associate Director: Michael Bolognesi MD
SBR Manager – Research Practices: Molly Gavigan RN JD
SBR Manager – Financial Practices: Gloria Pruett
Other:
Executive Director – Michael Gagnon MBA
Orthopaedic Surgery Finance Manager – John Tyrrell CFP

3. **Define Clusters & Leadership within Clusters:**
Clusters within the Department of Orthopaedic Surgery will align with the Sectional Structure. Each Section will be responsible for its research focus.

<table>
<thead>
<tr>
<th>CLUSTER RESEARCH AREA</th>
<th>MEDICAL DIRECTOR</th>
<th>LEAD COORDINATOR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Foot / Ankle</td>
<td>James Nunley MD</td>
<td>Jennifer Friend</td>
</tr>
<tr>
<td>Hand / Upper Extremity</td>
<td>David Ruch MD</td>
<td>Suzanne Finley</td>
</tr>
<tr>
<td>Joint / Adult Reconstruction</td>
<td>Michael Bolognesi MD</td>
<td>Suzanne Finley</td>
</tr>
<tr>
<td>Oncology</td>
<td>Brian Brigman MD</td>
<td>Molly Gavigan</td>
</tr>
<tr>
<td>Pediatrics</td>
<td>Robert Fitch MD</td>
<td>Molly Gavigan</td>
</tr>
<tr>
<td>Spine / Disc</td>
<td>Christopher Brown MD</td>
<td>Cameron Howes</td>
</tr>
<tr>
<td>Sports Medicine</td>
<td>William Garrett MD</td>
<td>Molly Gavigan</td>
</tr>
<tr>
<td>Trauma</td>
<td>Robert Zura MD</td>
<td>Maria Manson</td>
</tr>
</tbody>
</table>
4. Faculty Advisory Board
   Composition:

   The Orthopaedic Surgery Clinical Research Committee [OSCRC] will consist of the SBR Key personnel and Divisional Research Leaders (either Medical Directors or Division Chief)

   Members:
   • Orthopaedic Surgery Clinical Research Core Committee [OSCRCC]
     • Director: Steven Olson MD
     • Associate Director: Michael Bolognesi MD
     • SBR Manager – Research Practices: Molly Gavigan RN JD
     • SBR Manager – Financial Practices: Gloria Pruett
   • Other Key Personnel
     • Department Executive Director: Michael Gagnon MBA
     • Department Finance Manager: John Tyrrell CFP
   • Orthopaedic Division Research Leadership
     • Foot & Ankle: James Nunley MD
     • Hand & Upper Extremity: David Ruch MD
     • Joint & Adult Reconstruction: Michael Bolognesi MD
     • Oncology: Brian Brigman MD
     • Pediatric: Robert Fitch MD
     • Spine: Christopher Brown MD
     • Sports Medicine: William Garrett MD
     • Trauma: Robert Zura MD
   • Resident Representative: the Chief Resident that is serving as “Administrative Chief” at the time of each quarterly meeting

   Term of Members:
   The faculty advisor will be appointed for a three year term and will be eligible for reappointment. Appointment to faculty advisor is based on the faculty member having experience in clinical research as PI, having current all required IRB and institutional training requirements and a full-time appointment in the Department of Orthopaedic Surgery.

   Frequency of Board Meetings: Quarterly and ad-hoc as needed.

   Function: (Please define how studies will be evaluated and how selection decisions will be made.)
The responsibilities of the SBR Leadership are the following:

- Evaluate the merit of each proposal
- Evaluate the feasibility of all clinical research protocols regarding administrative and clinical support needs from physicians and research staff
- Evaluate proposed budgets for fiscal solvency
- Ensure that all protocols and division members engaged in clinical research meet the institutional standards for compliance and financial reporting as designated by the Clinical Research Support Office (CRSO)
- Serve as a resource for trainees conducting clinical research
- Review the progress of on-going clinical research protocols
- Provide a forum to discuss questions and challenges related to the conduct of clinical research in the Department of Orthopaedic Surgery

The process of how studies are evaluated is as follows:

New Clinical Research Projects: All new projects submitted via IRB with an Orthopaedic Surgery SBR designation will be reviewed in the following manner:

- The Principal Investigator submits a new Clinical Research Project Application from one of the Divisions/Clusters within the SBR including but not limited to: protocol, research summary, informed consent form, budget, etc
- The following reviews occur simultaneously:
  - Faculty member for scientific merit, enrollment feasibility (patient base) and competing studies, involvement of other departments and facilities, etc
  - SBR Financial Practice Manager or Department Financial Manager will perform a budget review to determine if study is financially feasible
  - Lead Coordinator for logistical feasibility and manpower
  - Division Chief for financial feasibility and ultimate financial support
- The OCRCC will review and The SBR Director will make the following recommendations to the Department Chair and ultimately to the PI:
  - May recommend submission to IRB with no changes
  - May recommend revisions of the protocol or budget before submission to the IRB is granted
  - May deny the proposal request
- Recommendation / Feedback to the PI by the SBR review process will occur within 7 days.
- Each new project requires sign off by Department Chair.
- Appropriate designees will be assigned for review when there are conflicts of interests
On-going Clinical Research Projects:

- On a quarterly and ad-hoc basis, the faculty Advisory Board will review the Orthopaedic Surgery clinical research projects based upon the following milestones / issues:
  - financial status
  - serious adverse events/deaths
  - enrollment (present, potential, issues, etc.)
  - personnel issues
  - study conduct issues (i.e., billing, etc.)
  - study closures
  - audits
  - IRB lapses
  - CRSO issues
  - Compliance (training)
5. SBR Governance and Financial Plan:

**Reporting Structure**
- The Orthopaedic Surgery SBR reports to the Chairman of Orthopaedic Surgery through the SBR Director and Departmental Administrative structure.
- The Orthopaedic Surgery SBR also reports to the SBR Leadership in the CRSO.

**Financial Structure**
- The cost of the central SBR staff will be funded by a combination of the following:
  - Department / Chair Discretionary Funds
  - Allocation of funds from individual clinical trials (see Levels below)
  - Percentage of margin on closed trials (refer to margins and deficits below)
  - The Department will require each PI to backstop their individual research operations with discretionary funds, and each Division to back-stop it’s research faculty
- Clinical Research Projects in the Department of Orthopaedic Surgery will include an administrative allocation that will be retained from each project as defined by the following Levels:

  **Level 1**  Minimal Risk Studies WITHOUT Consent (e.g.: Chart Review, Database Analysis)
  **Level 2**  Minimal Risk Studies WITH Consent; NO billing risk (e.g.: Database/repository with data/specimen collection, Survey-outcomes)
  **Level 3**  Minimal Risk Studies WITH Consent; WITH billing risk (e.g.: Database/repository with data/specimen collection, Survey-outcomes)
  **Level 4**  Greater than Minimal Risk NO billing Risk (e.g.: interaction/Intervention no DUHS bills generated)
  **Level 5**  Greater than Minimal Risk WITH billing Risk (e.g.: Therapeutic Clinical Trial – Interaction/Intervention DUHS bills generated)

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

**Margins:**
A percent of the aggregate residual at the closeout of the study will be transferred to the Orthopaedic Surgery SBR. The percent will be transferred when all clinical research project-related activities have been completed (i.e., Final Report to the IRB, verification of expenses and revenue, invoicing, etc.).
Deficits:
Deficits will be managed by the discretionary funds of the PI and will be reviewed on a case by case basis to ensure solvency of investigators research operations. Deficits will be backstopped by each Division.

NOTE: Tier fees, margin residual fees will be negotiated annually.

6. SBR Stakeholders: (Including but not limited to:)

Please list the SBR Stakeholders, which could include departments, centers, institutes, CSUs and schools.

- Patients that participate in SBR studies
- Investigative teams that conduct this research and
- all Duke entities they interface with, including but not limited to, the Departments of Radiology, Anesthesiology, Pediatrics, Oncology, Pharmacy, Surgery, Family Medicine, Physical Therapy, Psychiatry, Pathology, Academic Departments (Cell Biology, etc), Medicine (Rheumatology, etc), Biological Anthropology; Clinical Support Units (CSUs), Centers and Institutes, Duke Hospitals, Duke Schools
- NIH, all industry sponsors and foundations,
- All trainees,
- All other academic organizations
- Offices of CRSO, IRB, OCRC, ORA and OSP

7. Communication Plan:

Please describe how information about the SBR will be actively communicated to SBR faculty and staff.

- The Orthopaedic Surgery SBR leadership will attend the various CRSO weekly meetings [Medical Director meetings, Financial Practice meetings, Research Practice meetings, Joint RP/FP meetings, Advisory Board meetings, ad-hoc meetings, etc]
- The SBR leadership team [OSCRCC] will hold weekly leadership meetings
- The Financial and Research Managers will meet twice a month with Lead Coordinators
- Ortho Faculty Advisory Board meetings will meet on a quarterly basis
- Divisional Research Financial Status will be reviewed quarterly
- The Orthopaedic intranet/website will include information about the Orthopaedic SBR. Components will include: Announcements, Contacts, Guides, Policies and procedures
- Open forums and one-on-one meetings with Faculty members will be scheduled as necessary.
- Updates will be given at the Orthopaedic Surgery Senior Staff Meetings by the SBR Director.
4. (Continued) Insert Organization Chart:

- Department Chair: J NUNLEY
- Finance Manager: J TYRRELL
- Financial Practices Lead: G PRUETT (7/6/10)
- SBR Director: S OLSON
- SBR Faculty Advisory Board
- Research Practices Lead: M GAVIGAN
- Divisions / Principal Investigators
- CRCs Research Staff

CRSO