

Site-Based Research Charter

Duke University School of Medicine

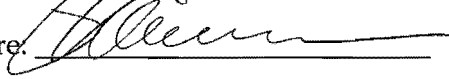


DUKE UNIVERSITY SCHOOL OF MEDICINE

Name of SBR: **Anesthesiology**

Date: 1/5/2010

SBR Director Signature: 

Unit Head Signature: 

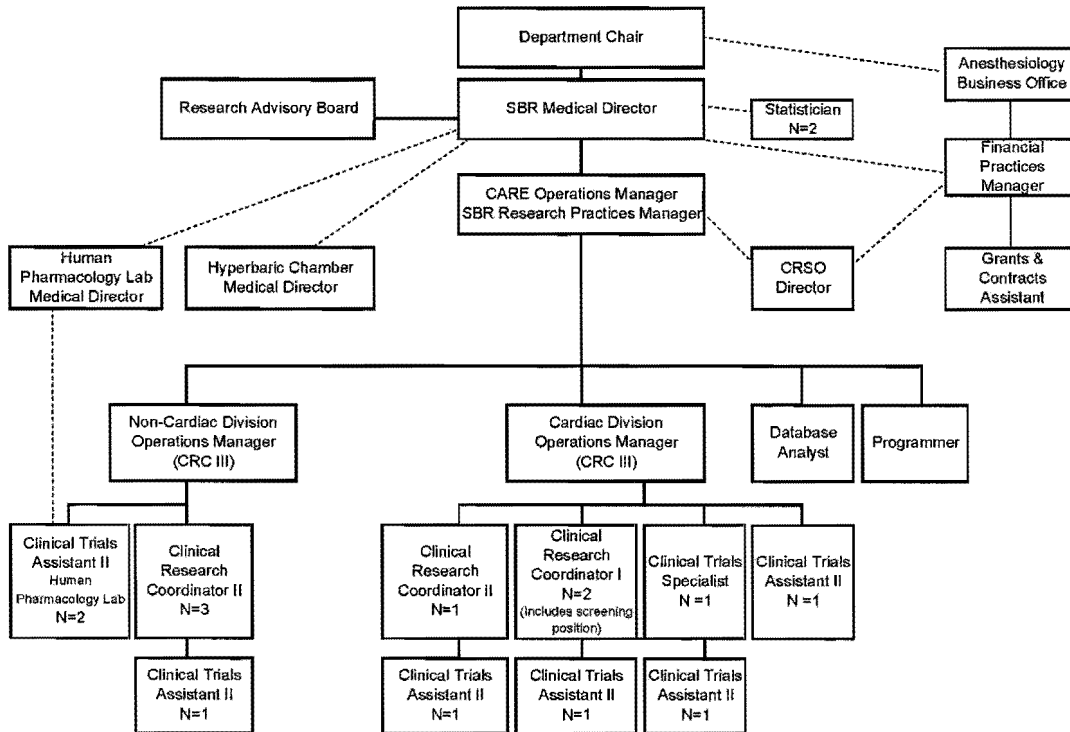
1. Scope of Research within the SBR:
All clinical research conducted in the Department of Anesthesiology will be managed by the SBR. As part of the triad within the Duke Heart Center, it is anticipated that research conducted within the Division of Cardiothoracic Anesthesiology will overlap considerably with that of the Division of Cardiothoracic Surgery in the Department of Surgery and to a lesser degree, that of the Division of Cardiology in the Department of Medicine.

2. Key Personnel:
Director: Joseph P. Mathew, MD
SBR Manager – Research Practices: Bonita L. Funk, RN, CCRP
SBR Manager – Financial Practices: Zarrin Brooks
Other: Cluster Leads: Roger Hall, AS (Cardiac Division) and Narai Balajonda, MD (Noncardiac Division)

3. Define Clusters & Leadership within Clusters;
See chart next page



Organizational Structure of the Anesthesiology SBR



4. Faculty Advisory Board

Composition:

The Faculty Advisory Board (internally called the Research Advisory Board or RAB) members were appointed by the Chair of the Department of Anesthesiology to represent the broad spectrum of research conducted within the department and includes the following personnel:

- Elliott Bennett-Guerrero, MD (chair)
- Atilio Barbeito, MD
- Bonita Funk, RN, CCRP (non-voting member)
- TJ Gan, MD
- Ashraf Habib, MD
- Joseph Mathew, MD (SBR Director)
- Richard Moon, MD
- Mark Newman, MD (Department Chair)
- Anthony Roche, MD
- Andrew Shaw, MD
- William White, MPH



The term of service for each member of the RAB is 5 years. Appointment and re-appointments to the membership of the RAB are at the discretion of the Chair of the Department of Anesthesiology. The RAB will meet on an as needed basis, upon request of the SBR Director or any member of the RAB.

Function:

The purpose of the RAB is to provide advice to the SBR Director and the Chair of the Department of Anesthesiology on the conduct of clinical research within the department. It is anticipated that the RAB will make recommendations on a variety of research related issues including but not limited to study evaluation and selection, margin distribution, funding of departmental pilot grants and enrollment prioritization. When the RAB is called to session by the Chair of the RAB, a quorum of 7 of the 10 voting members is required to pass ensuing recommendations. With regards to the evaluation of an unfunded or under-funded study, a specific plan has been formulated as follows: The Chair of the RAB will select 2 other voting RAB members on a rotating basis, and he and these other 2 members will serve as the subcommittee for evaluating the project. Subcommittee members will be chosen so as to avoid any potential conflict of interest. Studies in question will be reviewed by the 3 subcommittee members in the presence of the Primary Investigator, the SBR Director, and any relevant SBR personnel and subsequently voted on (anonymously). The recommendation of the subcommittee will then be implemented.

5. SBR Governance and Financial Plan:

The Anesthesiology SBR is accountable to the Chair of the Department of Anesthesiology as defined in the organization chart above. Funding for the SBR infrastructure will be provided by

- a) an additional overhead on all externally funded projects other than those funded by the federal government or national funding agencies such as the American Heart Association
- b) a portion of the residual funds from pharmaceutical studies.

The Department of Anesthesiology will ultimately provide the financial backstop for the SBR from the indirect funds being returned to the Department by the University.

The following responsibilities will be delegated to the Departmental IRB Reviewer for all clinical protocols in the Anesthesiology SBR:

- a) evaluation for the safety and welfare of research participants
- b) determination of clinical feasibility
- c) evaluation of the supporting scientific and/or medical information
- d) determination that this protocol does not duplicate existing published studies
- e) determination that the background, methods and analytical plan are appropriate to answer the research question being asked

6. SBR Stakeholders:

The Department of Anesthesiology is currently the only stakeholder in the Anesthesiology SBR.



7. Communication Plan:

SBR information will be communicated to SBR staff using the following two mechanisms:

- 1) The SBR leadership team comprised of the Medical Director, Research Practices Manager, Cluster Leads and Financial Practices Manager hold biweekly leadership meetings
- 2) The Medical Director, Research Practices Manager, Cluster Leads and all the Clinical Research Coordinators and Clinical Trials Assistants meet twice a month for a "Nuts and Bolts" session.

SBR information will be communicated to SBR faculty via the departmental website, e-mail, the weekly departmental newsletter, and/or at monthly departmental faculty meetings. Information relevant to isolated investigators will be shared on a one-on-one basis by the Medical Director, Research Practices Manager, Cluster Leads, and/or the Financial Practices Manager.