


# Neurosurgery Clinical Research Oversight Charter

Name of Oversight Organization: Neurosurgery

Date Form Completed: 7/10/2017

Oversight Organization Director Signature:  MD

Unit Head Signature: 

## 1. Scope of Research within the Oversight Organization:

Duke University Health System Institutional Review Board (DUHS IRB) approval is required for all studies involving human subjects that utilize Duke University Health System (DUHS) patients, patient information, resources (equipment or personnel), or services that generate a Maestro Care charge. The operating business units responsible for the integrity, financial accountability, regulatory compliance, quality, and academic productivity of clinical research studies are the School of Medicine's site-based Clinical Research Units and Oversight Organizations [per the Duke Office of Clinical Research (DOCR) policy: [Scope of Oversight and Responsibility of Clinical Research](#)].

The Neurosurgery Oversight Organization is a collaboration between the Duke Office for Clinical Research, The Research Administration Support Resource, and the Duke School of Medicine Department of Neurosurgery. All research involving human subjects being conducted by investigators with a primary appointment in the Department of Neurosurgery, with the exception of oncology studies (specifically studies that meet the definition of cancer studies), will receive support and operational oversight from DOCR and scientific oversight from a Neurosurgery faculty review committee led by Dr. Peter Fecci.

The Duke Department of Neurosurgery engages in basic, translational and clinical research focused on conquering diseases of the nervous system. Research teams are led by a productive group of clinically active neurosurgeons, neuro-oncologists, surgeon scientists and eight dedicated PhD researchers.

This Oversight Plan outlines the steps necessary to allow for efficient protocol approval and start-up for studies submitted through the DUHS IRB that fall within the DOCR Oversight Organization portfolio, specific to Neurosurgery studies. Certain functions (detailed below) will be the responsibility of the Neurosurgery Oversight Organization, however, the primary responsibility for maintaining research integrity shall remain with the Investigator.

During proposal and protocol development, please feel free to contact the manager of the Oversight Organization (Alifia Hasan, [alifia.hasan@duke.edu](mailto:alifia.hasan@duke.edu)) and/or schedule a study-planning meeting with DOCR staff (email [docr-studyplanning@dm.duke.edu](mailto:docr-studyplanning@dm.duke.edu)).

## 2. Key Personnel:

Medical Director: Peter Fecci, MD, PhD

Research Practice Manager: DOCR

Financial Practice Manager: RASR

Data Practice Manager: DOCR

Oversight Organization Manager: DOCR

Neurosurgery Research Manager: Beth Perry

Neurosurgery Administrative Director: Kathy Tobin

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### 3. Define Clusters and Leadership within Clusters:

Cluster	Leadership
Duke Brain Tumor Immunotherapy Program	John H. Sampson, MD, PhD, MBA, MHSc
Oncolytic Immunotherapy Laboratory	Matthias Gromeier, MD
Epilepsy Lab	Michael M. Haglund, MD, PhD
Functional Neurosurgery/Neurophysiology Lab	Dennis A. Turner, MD
Duke NeuroInnovations	Nandan Lad, MD, PhD
Pediatric Brain Tumor Research Laboratory	Eric Thompson, MD
Duke Spine Center	Robert E. Isaacs, MD, Oren N. Gottfried, MD, and Isaac O. Karikari, MD
Neurovascular Lab	Ali R. Zomorodi, MD, and L. Fernando Gonzalez, MD
Duke Neuro-Outcomes Program	Nandan Lad, MD, PhD

### 4. Advisory Council and Scientific Review process

**Council Composition:**

*Director, Peter Fecci, MD*

*Statistical Advisor*

*Neurosurgery Finance and Administration Advisor*

*Research Practice Manager*

*Data Practice Manager*

*Financial Practice Manager*

**Function:** The committee will meet quarterly with the responsibility of reviewing and providing recommendations regarding institutional standards and systems for the conduct of clinical research (including principal investigator and study coordinator training and certification, standard operating procedures, etc.) and providing guidance in the development and implementation of standardized tools and resources for clinical research (including budget templates, financial reports, project evaluation tools, study management tools, etc.)

The Scientific Review Committee will review the scientific integrity of newly proposed research projects ad hoc.

**Scientific Review Process:** New studies will be reviewed by the RPM and sent to the scientific Director to initiate the review process. The Director will assign a reviewer based on area of expertise.

*Clinical Research projects will be reviewed for:*

- Scientific relevance
- Appropriate manpower
- Patient base
- Facilities

Operational feasibility and financial feasibility will be determined by collaborating managers within the Oversight Organization.

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Upon recommendation, the scientific review committee will send the research project to the Director for final Oversight Organization approval prior to IRB consideration.

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### 5. Oversight Organization Governance and Financial Plan:

Financial governance will be provided by the Department of Neurosurgery Administration in collaboration with the Research Administration Support Resource (RASR) as defined in the RASR service level agreement.

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### 6. Stakeholders:

- Department of Neurosurgery
  - Brain Imaging and Analysis Center
  - Duke Biomedical Engineering
  - Duke Cancer Institute
  - Duke Clinical & Translational Science Institute
  - Duke Global Health Institute
  - Pediatric Brain Tumor Foundation Institute at Duke
  - The Preston Robert Tisch Brain Tumor Center
  - Duke Global Neurosurgery and Neurology
  - Brain Tool Laboratory
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### 7. Communication Plan:

1. Faculty engagement: Introduction of the new Oversight Organization structure, processes, and contacts will be made to Neurosurgery Faculty in the context of pre-existing departmental meetings or individual faculty meetings.
2. Research Staff engagement:
  - a. Oversight Organization informational sessions/town halls to introduce the structure and the contacts, 1:1 discussions as needed.
  - b. Regular (monthly) staff meetings to disseminate new information (regulations, policies, new offices, new services, etc) and to gather information and needs.
  - c. Email and online communications.
  - d. Policy, regulations, and training updates via the DOCR website
3. Neurosurgery Administration engagement: Quarterly meetings will be held including Neurosurgery administrators, representatives from DOCR and RASR, and a Biostatistical Faculty member to discuss processes, milestones, and any needed effort adjustments.

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## Organizational Chart:

