

Neurology

Site-Based Research Charter



Name of CRU: **Neurology**

Date: 2/28/2013

A handwritten signature in black ink that reads 'James R. Burke MD, PhD'.

CRU Director Signature:

(James R Burke, MD, PhD)

Unit Head Signature: _____

1. Scope of Research within the Neurology CRU:

The scope of the Neurology Clinical Research Unit (CRU) includes all clinical research and regulatory oversight that is conducted in the Department of Neurology, including the following Divisions: General Neurology, Behavioral Neurology, Critical Care, Movement Disorders, Epilepsy and Sleep, Neuromuscular, Multiple Sclerosis and Neuroimmunology, Pain, and Stroke and Vascular Disease.

The Neurology CRU 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. Neurology CRU Key Personnel:

Director: James R. Burke, M.D., Ph.D.
– Research Practices Manager: Lisa Gauger
Financial Practices Manager: Megan Phillips
Regulatory Administrator: Donna Carnes
Neurology Business Manager – Ronald Beauvais

3. Define Clusters & Leadership within Clusters;

No clusters

**4. Faculty Advisory Board
Composition:**

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The Neurology Clinical Research Advisory Committee will consist of the CRU Key personnel and Divisional Research Leaders

Members:

Neuromuscular: Donald Sanders
Pain: Timothy Collins
Movement Disorders: Burton Scott
MS & Neuroimmunology: Mark Skeen
Epilepsy & Sleep: Aatif Husain
Behavioral Neurology: James Burke
General Neurology: Danny Laskowitz
Critical Care: Carmelo Graffagnino
Stroke & Vascular: Larry Goldstein
Residency and Fellow Education: Saurabh Sinha

Term of Members:

The advisory committee members will be appointed for a three year term and will be eligible for reappointment by the Division Chief for the appropriate section. Appointment to the advisory committee is made by the Division Chief of the appropriate section based on the faculty member having experience in clinical research as PI, being current on all required IRB and institutional training requirements and having a full-time appointment in the Department of Neurology.

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 CRU Leadership are the following:

- Evaluate the merit of each proposal, including a review of statistical plan. If statistical assistance is required it will be requested from the Department of Biostatistics and paid for by the PI.
- Evaluate the feasibility of all clinical research protocols regarding administrative and clinical support needs of 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 Duke Office of Clinical Research (DOCR).
- 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 Neurology

The process of how studies are evaluated is as follows:

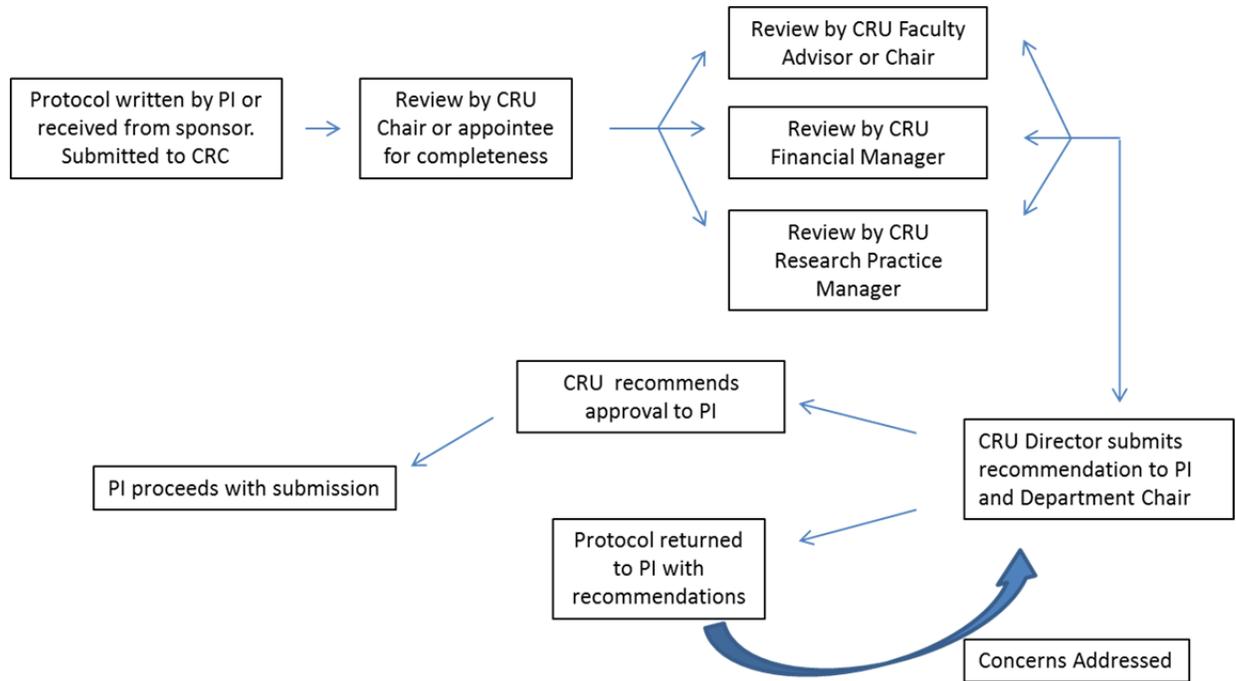
New Clinical Research Projects: New projects submitted to the Neurology CRU designation will be reviewed in the following manner:

- The Principal Investigator submits a new Clinical Research Project Application including but not limited to: protocol, research summary, informed consent form, proposed budget, etc.
- The PI signs a Memorandum of Understanding (MOU) noting research and financial responsibilities. In the event that the PI has insufficient funds the MOU can be signed by another faculty member or group of faculty members.
- The application is reviewed by the CRU Regulatory group for completeness and submitted for SBR review.
- Concurrent review is then performed by the following groups:
 - A Faculty member who is a member of the Advisory Committee is assigned to review the protocol for scientific merit, statistical plan, enrollment feasibility (patient availability) and competing studies, involvement of other departments and facilities, etc.
 - CRU Financial Practices Manager in consultation with the Research Practices Manager will perform a budget review to determine if study is financially feasible.
 - Research Practice Manager will review for logistical feasibility and manpower assessment.
 - Regulatory Administrator will ensure registration of studies with clinical trials.gov when indicated.
 - The Medical Director of the Neurology CRU, Division Chief and Department Chair, or his appointed delegate, will review for financial feasibility.
- The reviews will then be submitted to the CRU Medical Director who will make the following recommendations to the Department Chair, or his appointed delegate, and ultimately to the PI:
 - Submission to IRB with no changes.
 - Revisions of the protocol or budget before submission to the IRB.
 - Deny the proposal request.
 - When project is in final form it must be signed by Department Chair before

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implementation.

- Recommendation / Feedback to the PI by the CRU review process will occur within 7 days.
- Each new project requires sign off by Department Chair or his appointed delegate.
- Appropriate designees will be assigned for review when there are conflicts of interests



Neurology CRU evaluation of Proposals process.

On-going Clinical Research Projects:

- On a quarterly and ad-hoc basis, the faculty Advisory Board will review the Neurology Advisory Committee will review all clinical research projects based upon the following milestones / issues:
 - Serious Adverse Events
 - Financial status
 - Enrollment (present, potential, issues)
 - Personnel issues
 - Study conduct issues
 - Study closure
 - Audits
 - IRB lapses
 - DOCR issues
 - Compliance (training)

5. CRU Governance and Financial Plan:

Reporting Structure

- The Neurology CRU reports to the Chairman of Neurology, or his appointed delegate, through the CRU Director and to the CRU Leadership in the DOCR.

Financial Structure

- The cost of the central CRU staff will be funded by a combination of the following:
 - The Department requires that each PI be responsible for his/her research operation, including backstopping research with discretionary funds, if needed.
 - Department / Chair funds
 - Allocation of funds from individual clinical trials
 - Percentage of margin on closed trials (see Margins below).
 - Memorandums of Understanding (MOUs) will be required for Departments that use the Neurology CRU services and must be co-signed by the PI and the originating Department Chair.

Clinical Research Projects in the Department of Neurology 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 Neurology CRU or when the fund code is assigned. Fees are subject to change. Tier fees, margin residual fees will be negotiated annually.

Margins:

A portion of the residual at the closeout of the study will be transferred to the Neurology CRU . Transfers will occur 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.

6. CRU Stakeholders: *(Including but not limited to:)*

Please list the SBR Stakeholders, which could include departments, centers, institutes, CSUs and schools. Patients that participate in CRU studies; Investigative teams that conduct this research and all Duke entities they interface with, including but not limited to, the Departments of Anesthesiology, Pediatrics, Oncology, Pharmacy, Radiology, Surgery, Family Medicine, Physical Therapy, Psychiatry, Pathology, Academic Departments (Cell Biology, etc), Medicine; Clinical Support Units (CSUs), Centers and Institutes, Duke Hospitals, Duke Schools; Durham Regional Hospital; Duke Health Raleigh; Duke Clinical Enterprise; Durham, VA Medical Center; Department of Veterans Affairs; NIH; Offices of CRSO, IRB, OCRC, ORA and OSP; all industry sponsors and foundations; trainees; External stakeholders include sponsoring organizations and academic institutions with whom our investigative teams collaborate.

7. Communication Plan:

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

- The Neurology CRU Key Personnel will attend the various DOOCR weekly meetings [Medical Director meetings, Financial Practices meetings, Research Practices meetings, , Advisory Board meetings, ad-hoc meetings, etc
- The CRU leadership team [NCRO] will hold biweekly leadership meetings
- The Financial and Research Managers will meet monthly with Coordinators
- Neurology Faculty Advisory Board meetings will meet on a quarterly basis
- Divisional Research Financial Status will be reviewed quarterly
- The Neurology intranet /website will include information about the Neurology CRU. Components will include: Announcements, Contacts, Guides, Policies and procedures
- Open forums, including Faculty meetings and Neurology Grand Rounds, and one-on-one meetings with Faculty members will be scheduled as necessary.

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4. (Continued) Insert Organization Chart:
Neurology CRU Organizational Chart

