

# Clinical Research Unit Charter

Name of CRU: Clinical & Translational Science Institute (CTSI)

Date Form Completed: September 4, 2018 (Revised)

CRU Director Signature: \_\_\_\_\_

Unit Head Signature: \_\_\_\_\_

---

## 1. Scope of Research within the CRU:

The Clinical & Translation Science Institute (CTSI) CRU will provide infrastructure, resources and support to assist Duke investigators, from any school at Duke University, translate ideas into innovations that improve health. The CTSI CRU will be responsible for the scientific integrity and relevance, regulatory compliance, financial accountability/feasibility and academic productivity of clinical projects conducted in the CTSI.

The organizational focus of the CRU will be projects that serve the institution and/or span multiple CRUs. Projects will be clustered as either (1) site-based research that spans existing CRUs (e.g. when investigators or project scope spans multiple department or CRUs) or (2) data-oriented studies that serve the institution where there is no other clear CRU home (e.g. Biostatistics & Bioinformatics). The faculty advisory board will develop clear criteria and the CRU Director will determine appropriateness for projects. Different levels of support will be provided based on the type of research being conducted within the CTSI CRU.

---

## 2. Key Personnel:

CRU Director: Evan Myers, MD  
CRU Research Practice Manager (RPM): Leah Bouk, MBA, CCRC  
CRU Financial Practice Manager (FPM): Catherine Brett

---

## 3. Faculty Advisory Board

### Composition:

The CTSI CRU Faculty Advisory Board (FAB) will include the Director of CTSI and the CTSI CRU Director.

### Function:

CTSI CRU FAB meetings will be held at regular intervals at the CRU Director's discretion. In addition to the CTSI CRU FAB members, the CRU Managers for Research and Financial Practices, CTSI Finance Director and CTSI Director(s) of Operations will be invited to attend. The CTSI CRU FAB will provide direction to and consult with the CTSI CRU in shaping the scientific portfolio of the CTSI CRU by determining/reviewing:

- Scientific relevance and soundness
- Infrastructure limitations (i.e., available staff and facilities)
- Financial feasibility
- Competing projects
- Available and accessible participant population(s)
- Other relevant issues (i.e., use of central funds, etc.)

NOTE: The Duke Office of Clinical Research (DOCR) can provide operational assistance through study planning/initiation meetings, as needed.

# Clinical Research Unit Charter

## 4. CRU Governance and Financial Plan:

The CTSI CRU will report to the Director of the Duke Clinical & Translational Science Institute. The CTSI CRU will reside in and report to the School of Medicine (SoM) as a separate and collaborating unit.

The CTSI will be responsible for the financial backstop for the CTSI CRU. Funding for the CTSI CRU will come from a variety of sources including, but not limited to:

- CRU Management Fee (commercial pharmaceuticals and biotech companies)
- CTSI (internal and external funds)
- Commercial/Industry
- Federal Government
- Gift funds
- Non-profit Organizations/Foundations/Educational Institutions
- Project residuals
- SoM indirect recovery and institutional support

The CTSI will comply with all federal, institutional and state policies and procedures regarding research involving human subjects.

The CRU Director will be responsible for developing and documenting a review and approval process to evaluate and select clinical projects submitted to the CTSI CRU. All new clinical projects will undergo review prior to acceptance into the CTSI CRU.

All agreements, budgets and internal cost assessments (ICAs) will be reviewed and approved by the CTSI CRU FPM or designee. The CTSI CRU FPM or designee will help identify a back-stop fund code (WBSE), with a sufficient balance, to cover unforeseen costs and coverage of unexpected losses. A memorandum of understanding (MOU) will be put in place in case of a deficit at the end of the clinical project.

The CTSI CRU will be responsible for achieving and maintaining a portfolio that is fiscally solvent, compliant with institutional, state and federal regulations and is scientific relevant. In addition, the CTSI CRU will be responsible for adhering to and developing financial and non-financial policies and procedures in accordance with institution-wide policies established by the DOCR regarding the conduct of clinical projects.

---

## 5. CRU Stakeholders:

The CTSI CRU stakeholders include, but are not limited to:

- any school at Duke University
- clinical and basic science departments
- clinical service units (CSUs)
- other CRUs
- other institutes and centers
- research participants
- research administration offices

Other stakeholders include academic partners, federal agencies, foundations and industry sponsors with whom the CTSI collaborate.

---

## 6. Communication Plan:

# Clinical Research Unit Charter

CTSI CRU information will be communicated via the CTSI intranet website, emails and meetings. The CTSI CRU will send out notifications regarding changes to institutional guidelines and policies regarding the responsibilities of the CRU, investigators, study personnel, etc.

Open forums and ad hoc meetings will be scheduled, as needed.

## Organizational Chart:

