

## **Northwestern Cardiovascular Research Institute-Clinical Trials Unit**

### ***Non-Funded Research: Request for CTU Support***

The Clinical Trials Unit (CTU) is committed to providing research support services for non-funded projects on a case-by-case basis. Due to limited resources available it is necessary for the CTU to evaluate the scientific merit and feasibility of each project. This application process has been developed to make the resources of the CTU available to a wide spectrum of applicants. The following information provides additional information on the submission and approval process.

#### **Submission and review information**

- Any qualified investigator from the Departments of Cardiology or Cardiothoracic Surgery may submit a request for the CTU to provide assistance on a non-funded research project. Note: The CTU is currently unavailable to provide support for basic science research
- The Medical Director of the Clinical Trials Unit (Alan Kadish, MD) and the Co-Director of the Bluhm Cardiovascular Institute (Patrick McCarthy, MD) will review and approve all requests.
- The Request for CTU Support Form needs to be completed in its entirety; incomplete forms will be returned without review.
- Support will only be granted to projects that demonstrate scientific merit.
- The proposed research questions should be logical and comprehensive.
- The anticipated timeframe from submission of this request to notification of approval (or denial) is approximately 7 business days.
- For denied projects, feedback will be provided to the requesting investigator. Projects may be resubmitted for review.
- Approved requests will be executed in the order received.
- For multiple service requests, the CTU may not be able to provide support for all requested services (i.e. statistical support [8 hours] provided by the CTU for no charge, but \$2500 will be charged for completion of regulatory paperwork). This will be determined on a case-by-case basis.
- In cases where the Investigator's request exceeds available CTU resources, the following charges may apply:
  - Regulatory Preparation fee (initial review): \$2,500
  - Protocol development: \$60.00/hr
  - Statistical support: \$60.00/hr
  - Data entry support: \$28.00/hr

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**Date of Request:**

**Principal Investigator:**

**Department:**

**Phone:**

**Fax:**

**Email:**

**Co-Investigator(s):**

**Study Title:**

**CTU Services Requested (check all that apply):**      **Date needed:**      **Start:**      **Stop:**

**Regulatory-New IRB Project Submission**

**Protocol Development**

**Data Services:**

**Statistical support:**

- Data Entry
- CRF Generation
- Data Prep for Manuscripts
- Report Generation
- Quality Assurance

- Statistical Design
- Sample size/power calculations
- Data preparation/analysis
- Manuscript consultation
- Other:

**Other, specify:**

Is this your first request for CTU services on this project?      YES      NO

Have you received funding for this project?      YES      NO

Have you submitted or will you request funding for this project?      YES      NO

If yes, please identify:

If not, why?

Do you anticipate submission of an abstract/manuscript/poster presentation from this project?      YES      NO

Explain:

Do you have discretionary or other funding that can be used to support the requested services?      YES      NO

If so, what amount of funding can be used to support this project?

Describe the scientific merit of this project and why this request should be granted.

