

REQUEST FOR APPLICATIONS
Duke Clinical Research Unit
Research Pilot Project Awards
Funding Period March 1, 2009 - June 30, 2010

I. PROGRAM OVERVIEW

A. PURPOSE

The Duke Clinical Research Unit (DCRU) is a Duke resource available to investigators with any phase of clinical trials in either adult or pediatric populations. For non-commercial clinical trials funded by NIH, foundations, investigators' departments, and similar funding mechanisms, the DCRU provides, at no charge:

- space,
- nursing support,
- core laboratory support,
- statistical support for study design and analysis, and
- metabolic kitchen support

A new DCRU Pilot Project seeks to support investigators by offering partial funding for NIH and investigator-initiated studies utilizing DCRU services. This funding may be used to support outpatient services including laboratory tests and ancillary services.

Grants between \$500 and \$10,000 are available to support these studies.

The DCRU is a part of the Duke Translational Medicine Institute.

B. KEY DATES

Awards will be made until all of the allocated funds are obligated.

Application Submission Deadline: **Rolling**

Final Selection: **Rolling**

Funding Cycle Begins: **March 1, 2009**

Note that awards will be made on a rolling basis as applications are received, until all available funds are committed. Therefore, the DCRU encourages applicants to submit proposals as early as possible.

C. FUNDING DETAILS

The DCRU intends to fund as many projects as possible until the maximum amount available is committed. Awardees will be given access to DCRU facilities and nursing services, **plus additional funding between \$500 and \$10,000**. This funding may be used to support outpatient services such as laboratory tests, or other ancillary costs of a clinical research initiative. If additional funding is made available to the DCRU, additional applications will be considered, evaluated, and possibly accepted.

\$100,000 in funding is available through June 30, 2009. At the current time, the DCRU anticipates that an additional \$100,000 will be made available to fund this pilot program for the year starting July 1, 2009.

D. REQUIREMENTS

- The project must be a clinical research trial involving human subjects. Any phase trial will be considered for funding. Trials may involve either adult or pediatric subjects.
- Primary funding for the trial must be from NIH, another government agency, a foundation, investigator, departmental, or institutional funds.
- Investigators should be at the Instructor, Assistant, Associate or Professor level.
- Studies may be **ongoing studies or new studies**. New studies should be sufficiently advanced so that they can start within 6 months of application submission. Preference will be given to studies that can start sooner.
- At least some portion of the trial must be performed using DCRU services and/or facilities. Examples of services that the DCRU can make available to investigators include: phlebotomy, sample processing, and nursing support. Investigators may request the assistance of a DCRU project leader in identifying the DCRU services that are available to support a particular study.
- More than one proposal per faculty member acting as a PI may be submitted.
- If funded, investigators agree to the following requirements:
 - Investigators agree to submit semi-annual progress reports on the project status to the DCRU Scientific Advisory Committee (SAC).
 - Funding amount and/or duration may be modified pending Investigator and SAC agreement.
 - Requests for no-cost extensions (carryovers) will not be approved.
 - Any publications that are the direct result of this funding must reference: "Supported in part by the Duke Clinical Research Unit. The project described was supported by Grant Number 5UL1RR024128-03 from the National Center for Research Resources. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Center for Research Resources or the National Institutes of Health."
 - Investigators agree to notify the DCRU about publications related to this project, at the time of publication, and to provide copies of those publications to the DCRU.
 - If the project receives funding from NIH or another government agency, to provide the grant number associated with the project.

E. OVERALL REVIEW PROCESS

The review process will include submission of an application by e-mail to DCRU@mc.duke.edu.

While **all** non-commercial studies will be considered for this award, preference will be given to studies that:

- Are an on-going study funded in whole or in part by NIH or another government agency
- Are a new study funded in whole or in part by NIH or another government agency
- Are studies where DCRU funding is critical for successful completion of the project
- Are submitted earlier in the review process, as awards will be made on a rolling basis, until all funds are committed
- The amount of funding requested, up to the limit described in this RFA, will not be a consideration in selecting between competing applications

II. APPLICATION PROCESS

A. APPLICATION PROCESS

1. The Principal Investigator must prepare and submit the application to DCRU@mc.duke.edu.
2. Applicants will be asked to provide the following information:
 - a. Co-Investigators: Name, faculty level, department, division/specialty, contact information, and role on project.
 - b. General project information:
 - i. Therapeutic area
 - ii. Special populations
 - iii. Other funding sources
 - iv. DCRU/DTMI core resources or consultative services to be utilized
 - c. Statement regarding why DCRU funding is critical for meeting proposed aims (100-word limit)
 - d. If this is an ongoing project, a summary of the protocol (maximum 2 pages)
 - e. If this is a new project, briefly describe the proposed project (maximum 2 pages), by including a brief summary of and the specific aims of your proposal
 - f. Trial Timeline
 - List the timeline for the trial, along with the approximate dates as to when DCRU funding will be needed.
 - g. Proposed budget, with budget justification
 - h. Biographical sketch for each investigator
3. Applicants should download and review the application, which is available at: <http://www.dcr.duke.edu/dcr/pilots/application>. Once completed, return the application, with the supporting documentation required, to DCRU@mc.duke.edu.

B. FINAL SELECTION

DCRU will review all applications. DCRU may contact the investigator for clarification of any questions raised by the application. All applications will be reviewed by the DCRU Program Director, and the Chair of the DCRU Scientific Advisory Committee, who will make the final determination as to which proposals will receive DCRU support.

III. MISSION AND INFORMATION ON THE DTMI AND DCRU:

Duke Translational Medicine Institute (DTMI):

The Duke Translational Medicine Institute (DTMI) was established in October 2006 with a grant from the National Institutes of Health, National Center for Research Resources (NCRR) Clinical Translational Science Award (CTSA), and its mission is to expedite the translation of new scientific discoveries into clinical practice, promote measurable improvements in community health, and make personalized medicine a reality.

The DTMI includes state of the art translational pillars including the Duke Translational Research Institute (DTRI), the Duke Clinical Research Unit (DCRU), the Duke Clinical Research Institute (DCRI), and the Duke Center for Community Research (DCCR). For a summary of general information pertaining to the DTMI, please see <http://dtmi.duke.edu>.

DTMI core resources currently include Biomedical Informatics, Biostatistics, Clinical and Translational Research Ethics, Law and Policy, Training and Education, Pediatrics and Pediatric Management, Nursing, and Regulatory Affairs (see: <http://www.dtmi.duke.edu/core-teams>).

For additional information on the NCRR and CTSA initiative, please see: <http://www.ctsaweb.org>

Duke Clinical Research Unit (DCRU):

The mission of the DCRU is to provide a unique model for the conduct of early phase clinical research that accelerates the development of new medical therapies by:

- Applying advanced technologies to better understand disease and predict drug response
- Combining medical and scientific expertise with operational excellence, efficiency and regulatory compliance
- Offering a hospital-based environment to maximize subject safety
- Studying special patient populations as well as healthy volunteers

The DCRU is capable of accommodating studies requiring either inpatient or outpatient services to both pediatric and adult volunteers. Current facilities include:

- 10 licensed hospital beds including 2 “infant family rooms”; including both “standard of care” and research services
- 3 proof of concept dormitory rooms accommodating 8 adult or 6 pediatric beds
- Outpatient facility with 3 infusion chairs and 2 exam/procedure rooms

For additional information on this funding opportunity or the DCRU's services, please contact Cathy Lavin, DCRU Director of Operations (919-668-2253; cathy.lavin@duke.edu), or John McHutchison, MD, DCRU Program Director (919-668-7193; mchut001@mc.duke.edu).