

# RadCCORE

Radiation Countermeasures Center of Research Excellence

**Request for Applications: Pilot Projects**  
**Submission Deadline: July 9, 2010**

## **Background**

The Radiation Countermeasures Center of Research Excellence (RadCCORE) is a network of academic medical centers whose primary focus is to bring deliverables to the national stockpile to mitigate the effects of radiation induced injury. We have structured this research consortium as a multidisciplinary research center to conduct basic and translational research to identify and evaluate new countermeasures and underlying biology, to move candidate products through the regulatory process, and to provide new or expanded education resources to improve expertise in radiobiology. For more information on RadCCORE research projects and support core facilities, please visit our website at: [www.radccore.org](http://www.radccore.org)

## **Description of the Pilot Project Program**

The goal of the Pilot Project Program is to allow investigators that have the potential to translate their research into deliverables for the treatment of victims of radiation injury. Successful pilot projects should facilitate subsequent application for independent follow on funding.

The RadCCORE Pilot Project research program will provide up to \$105,000 direct costs for one year of support for pilot studies. Investigators will also have access to the RadCCORE core laboratories and facilities. A description of these resources is available at our website.

Applicants are also advised to take advantage of the expertise available within other RadCCORE project teams. Funded investigators will be required to participate in RadCCORE meetings to give periodic progress reports and submit a final written report.

## **Eligibility**

Applicants must have a Ph.D., M.D., or equivalent degree and otherwise meet standard NIH requirements for a R01 application. Junior faculty and postdoctoral fellows may apply under the direction of a senior faculty mentor.

**Projects that require performance of work at more than one institution will not be accepted. Third party subcontracts are unallowable.**

## **Areas of Research Focus**

The pilot project program will not be used to support clinical trials. If you have any questions on the nature or scope of the proposed project, please contact Dr. Mark Dewhirst, Chair of the Developmental Projects Committee (see "Application Submission" section below). The NIH has identified the following priority areas:

### Basic and Translational Research

- Innate and adaptive immune system enhancement and reconstitution.
- Mechanisms of radiation injury and therapy at the systemic, organ, cell, and molecular levels; and identification and verification of potential targets for countermeasures for radiation injury.
- Mechanisms of secondary responses that mediate, exacerbate, or ameliorate damage and disease resulting from external or internal radiation exposure in different tissues.
- Long-term effects, such as cancer and fibrosis.
- New animal models and in vitro assays to test and evaluate promising countermeasures.

### Biodosimetry

- Off-the-shelf products, such as computer-run robotic systems to automate current biodosimetry assays.
- New biodosimetry devices and techniques.
- New biomarker assays.

### Focused Product Development for Radiological Medical Countermeasures

- Animal efficacy and toxicity studies, including studies of large animal models.
- Preclinical pharmacokinetics and pharmacodynamics.
- Activity screening and early development of post-exposure mitigation/treatment regimens.
- Development of new product formulations and limited cGMP manufacture.
- Development of new animal models to provide mechanistic, safety, and efficacy data to support FDA approval of new products for human use.

### **Application Format**

Please follow the current format and instructions for form PHS 398 observing the following page limits:

<b>Introduction</b>	1 page
<b>Specific Aims</b>	1 page
<b>Research Strategy (Item 5.5.3 of Research Plan)</b>	6 pages
<b>Biosketch (per person)</b>	4 pages

You may omit “Form Page 5: Budget for Entire Proposed Period of Support”.

The Introduction should include a statement of the potential impact of the proposed research on bioterrorism responses.

The Research Strategy should include explicit delineation of milestones and deliverables. A

brief description of how the proposed pilot project will facilitate obtaining further funding should be included. A statistical analysis plan must be included (see “Statistical Considerations” below).

**Animal Studies:** institutional assurances must be in place prior to final funding of any project. If animal studies are proposed, please be sure to include a completed NIH section “Vertebrate Animals” as appropriate (not subject to page limits).

**Clinical Specimen Studies:** institutional assurances must be in place prior to final funding of any project. If the use of human samples is proposed, please be sure to include a completed NIH section “Human Subjects Research” (not subject to page limits).

### Statistical Considerations

Awardees will be expected to review their experimental plan with the RadCCORE Computation Medicine Core prior to beginning their studies.

Each aim must have its own statistical section (e.g., Statistical Consideration for Aim x). Within each statistical section the primary statistical hypothesis/objective for that aim must be stated. The secondary, exploratory or hypothesis generating objectives for the aim should be stated clearly and separately within the statistical section.

If the primary objective is a hypothesis, the statistical decision rule must be clearly outlined. If not (e.g., building a classifier) pertinent details (e.g., validation) must be given. The sample size available for each primary objective must be provided. If the primary objective is a hypothesis, power calculations (or Bayesian counterparts) must be provided. A discussion about the clinical relevance and realism of the effect sizes must be provided. If no power calculations are provided, then the investigator must clearly state that what is proposed is a pilot study. A brief plan for the analyses of the secondary, exploratory or hypothesis generating objectives must be provided.

### Scoring

The applications will be ranked using the following criteria:

- Significance
- Investigator(s)
- Innovation
- Approach
- Environment

### **Budget limits**

Investigators from the Duke University system may apply for a maximum of \$105,000 **direct** costs and the F&A costs will be covered by the RadCCORE center grant. Investigators at other institutions may apply for a maximum **total** project costs of \$160,000. You will be responsible for paying your institution’s F&A costs from this amount. No further support for indirect costs is available. **The final award amount is dependent on the number of pilot project applications funded and the funds available from the NIH.**

Investigators should include travel funds sufficient to cover the costs of attending the RadCCORE annual meeting in Durham, NC.

Personnel costs should be no more than 50% of the total direct costs requested.

The following budget categories **will not** be supported: Capital equipment (\$5,000 or greater in cost), Patient care costs, **Third party sub-contracts**.

**Project Period:** Approved applications will be funded for the period August 1, 2010 – July 31, 2009.

### **Project Monitoring**

Projects will be monitored informally at regular teleconferences and formally reviewed by the Developmental Research Committee every six months. Funded investigators will be expected to attend teleconferences when requested and present updates on progress at the RadCCORE annual meeting.

Formal monitoring will include a progress report detailing the funds expended and the progress toward completion of the specific aims. This progress report following six months of funding serves mainly to allow the Developmental Research Committee to provide helpful feedback, and/or offer advice or assistance.

A final report is due within 30 days of the end of the project period.

### **Application Submission**

For questions about the nature or scope of scientific projects, contact:

Mark W. Dewhirst, DVM, PhD  
Gustavo S. Montana Professor of Medicine  
[dewhirst@radonc.duke.edu](mailto:dewhirst@radonc.duke.edu)

Applicants are strongly encouraged to contact Dr. Dewhirst prior to completing the application to discuss the suitability and feasibility of the proposed work. **Projects must be within the program research focus areas and must have clearly defined deliverables to be competitive.**

Applications should be submitted by the application due date **5:00 PM (Eastern) July 9, 2010** electronically. Electronic submissions are required. PDF format is preferred. Late or incomplete applications or applications not conforming to the page limits will not be reviewed.

Submit an electronic copy of the application to:

Joel Ross, PhD  
RadCCORE Program Director  
[ross0008@mc.duke.edu](mailto:ross0008@mc.duke.edu)