ANNOUNCEMENT OF FUNDS AVAILABLE FOR PILOT GRANTS
from the Fred Hutchinson Cancer Research Center/ University of Washington
Center for Medical Countermeasures Against Radiation (CMCR)
December 21, 2005

Pilot Project Application Submission Deadline: February 13, 2006 by 4 pm.

Funds are available from the Fred Hutchinson Cancer Research Center/University of Washington's newly established Center for Medical Countermeasures Against Radiation (CMCR) to support pilot projects.

The goal of the pilot projects is to fund novel ideas, not yet supported by preliminary data, and to incorporate new technologies that aim to develop dosimetry and medical products that will allow for dose-appropriate interventions that mitigate the effects of radiation exposure.

Faculty from the FHCRC, UW, other academic research centers as well as from the CMCR are eligible for this pilot funding (see Application Process, Section B, below for more details).

The application and funding guidelines are as follows: We will accept applications for up to $100,000 annual direct costs from FHCRC and/or UW faculty members. For applications from faculty outside the FHCRC and UW, applications are limited up to $150,000 in annual total costs (combined direct and indirect costs). Each pilot project will be supported for up to a maximum of two years and will require successful competitive renewal for the second year of funding. Applications for less than the maximum cost limit are also strongly encouraged. Funding should be requested in modules of $25,000. The budget requested must be justified by the scope of the scientific work that is proposed.

The projects will be scored for innovation, potential for addressing radiation protection and scientific merit. Areas of research and development interest for the CMCR program include, but are not limited to, the following:

- Products and regimens that mitigate and/or treat radiation injury post-exposure, with emphasis on broad activity, ease of administration, and safety;
- Current Good Laboratory Practice (cGLP) capacity to test and evaluate candidate products in appropriate animal models of radiation-induced syndromes;
- Combinations of therapeutic products to enhance efficacy;
- Products that protect against radiation injury pre-exposure;
- New product formulations that can be easily administered to all civilian populations;
- Innate and adaptive immunological enhancement and reconstitution mediated by cytokines, growth factors, defensins, hematopoietic cell transplantation, etc.;
- Minimally invasive biodosimetry devices and techniques, biomarker assays, and other automated biology-based, high-throughput diagnostic systems to rapidly assess levels and types of radiation exposure, and to assess tissue status early after exposure and during treatment and recovery stages;
- Rapid assessment of radiation damage and methods for tissue repair after partial body exposure;
- Low-dose radiation effects and prevention of long-term disease, such as fibrosis, organ dysfunction, and cancer; including models of accelerated disease that will facilitate research;
- Improved antibiotic and antiviral regimens to control post-exposure infection in the context of immunosuppression and trauma;
- Probiotic therapies to minimize pathogenic infection and restore mucosal health;
- Mechanisms of radiation protection, injury, or repair in the hematological, gastrointestinal, pulmonary, renal, cardiovascular, and central nervous systems, as well as the skin, soft tissue, and liver;
- Methods for the purification, expansion, and storage of hematopoietic stem or progenitor cells;
- New animal models of radiation protection, injury, or repair;
- In vitro screening assays for new drug or biologic candidates; and,
- Surrogate markers of early injury or drug/therapy efficacy in non-human primates and humans.

Preference will be given to those pilot studies that are thematically related to the current FHCRC/UW CMCR program. The FHCRC/UW CMCR research program focuses on the following areas: (1) dosimetry, to determine the dose of radiation exposure and (2) cellular and cytokine therapy for treatment of victims after radiation exposure. Specifically, the FHCRC/UW CMCR dosimetry projects focus on protein biomarker and quantitative RT/PCR analysis to determine the radiation exposure. There are three cellular therapy projects. The first project is to develop committed progenitor cells for transient protection from radiation induced hematopoietic syndrome until autologous recovery can occur. The next two projects involve treatment after higher doses of radiation. These include the study of major histocompatibility complex (MHC)-mismatched cord blood transplantation and MHC-haploidentical peripheral blood stem cells, with emphasis on engraftment and the control of graft-versus-host disease (GVHD).

The primary focus for the overall National Institutes of Health (NIH)/ National Institute for Allergy and Infectious Diseases (NIAID) sponsored CMCR program is to support basic, translational, and applied research leading to new medical countermeasures against radiological and nuclear exposures due to terrorist attacks. The CMCR programs are multidisciplinary and conduct basic and translational research to identify new medical countermeasures to mitigate the effects of radiation. In addition, the CMCR programs develop and validate animal models or in vitro assays to evaluate countermeasures or underlying biology. The ultimate goal of the CMCR program is to develop countermeasures that can be moved through the United States Food and Drug Administration (USFDA) regulatory process into the national stockpile.

The key purpose of the Pilot Research Projects is to fund novel ideas not yet supported by preliminary data, to develop or incorporate new technologies as they become available, and to foster new collaborations between members of different CMCR programs. We intend that such funding would allow an investigator to begin to rapidly pursue a new finding and accumulate evidence needed to make a new NIH funding application.

Clinical trials involving direct *in vivo* human testing of drugs or medical interventions will <u>not</u> be supported by this pilot project mechanism.

The proposals will be selected on the basis of scientific merit after evaluation by the FHCRC/UW CMCR Pilot Project Committee.

Completed Pilot project applications are due on Monday, February 13, 2006 by 4 pm.

The FHCRC/UW CMCR Pilot Project Committee will review the applications and score applications. Criteria used for judging pilot study proposals include:

1) Scientific merit: the prospects that the proposed research would, if successful, lead to a significant scientific contribution to the development of new medical products that will protect against, mitigate the effects of, and treat the short- and long-term consequences of radiation exposure due to terrorist attack.
2) Pilot projects are consistent with the strategic plan and the overall CMCR program goals.
3) The degree to which the proposal is designed to pursue a new finding or timely research opportunity.
4) The extent to which other funds are not available for the follow-up on a new finding or new avenue of research.
5) The prospects that the pilot study proposal will lead to development of external peer reviewed funding.

The Pilot Project committee will examine the top proposals and their budget requirements. Priority ranking may be used to justify a greater or lesser funding level of funding for one proposal than another, subject to previously stated limits.

APPLICATION PROCESS

A. **Application Format**: Applications should be in the format of the 2005 Pilot Fund Award Application that follows. The application should clearly outline the aims and the strategy of the project and why funding through this pilot-grant mechanism is appropriate.

1. On the cover page, include all of the requested project information and an abstract that states the primary hypothesis. The abstract should be written to be understandable by reviewers with diverse expertise.

2. The length of the written proposal is 2 pages maximum. One additional page can be used for figures and tables. In addition, references can use one additional page. The emphasis is on a clear and concise written presentation.

3. Include an NIH Biosketch in PHS 398 grant application format listing your current sources of funding and a one-line description of the primary goal of each funded grant. An NIH Biosketch should be included for each key personnel involved with the project. (Sample biosketch format can be found at: http://grants.nih.gov/grants/funding/phs398/biosketchsample.doc) In addition to the Biosketch information, please include pending awards and percent effort for the applicant for all funding sources.

4. Include a one-page budget summary, including justification for effort and supplies.

B. **Eligibility:** Applicants must be faculty members of the Fred Hutchinson Cancer Research Center, University of Washington, or other universities and research institutes. Faculty members must be eligible for independent NIH R01-type funding.

C. **Application Due Date**: Applications are due **Monday February 13, 2006 by 4pm. Please note that applications received after this deadline will not be accepted for evaluation by the Pilot Award Review Committee**. Applications will be completed using the NIH "just in time" mechanism.

D. **Application Submission**: Applications should be submitted by the February 13, 2006 application due date via email, interoffice mail, or hand delivery to Ms. Beckee Cruz, who will forward the documents to the CMCR Pilot Award Review Committee:

- Email: Submit an electronic copy of the application to Ms. Beckee Cruz at bcruz@fhcrc.org
- Interoffice/US postal service/ overnight express mail: Submit 10 complete copies of the application to:

  Ms. Beckee Cruz
  Box 358080, Mailstop D1-100
  Fred Hutchinson Cancer Research Center
  1100 Fairview Avenue North
  Seattle, WA 98109-1024
  (206)-667-6108

- Hand Delivery: Deliver 10 complete copies of the application to Ms. Beckee Cruz at D1-347 in the FHCRC Thomas Building at 1100 Fairview Ave N.

Contact information for Beckee Cruz: (206) 667-6108 or bcruz@fhcrc.org
Receipt of the submitted application will be confirmed by email from Ms. Beckee Cruz.

E. **Award Timeline:** Proposals received at the deadline for submission will be evaluated by the FHCRC/UW CMCR Pilot Project Committee. The announcement of provisional awards will be made by the CMCR Pilot Project Committee and is expected before March 15, 2006. After the announcement of the provisional award, the applicant will need to obtain approval from the relevant

institutional committees including IACUC, IRB, and safety committees. In addition, the applicant must then complete the detailed final budget with justification and other support documents and obtain signature by the individual authorized to sign for his/her institution. The completed application will be forwarded to the NIAID program staff for final approval. After NIAID administrative approval, the FHCRC/UW CMCR will release funding. We expect that release of funding will occur approximately 3 months after the provisional award is made.

F. **Questions**: If you have questions about the pilot award application process please contact Dr. George Georges, who is the principal investigator for the CMCR Pilot Project. Dr. Georges can be reached at (206) 667-6886 or ggeorges@fhcrc.org.

Administration of pilot projects. Successful Pilot Project applicants will be asked to submit a revised budget if the recommended funding level differs from the request, but they will not exceed the $100,000/year direct cost limit for FHCRC/UW or $150,000 total cost limit for other institutions. Fiscal administration of Pilot grants will be performed by Ms. Beckee Cruz, Fred Hutchinson Cancer Research Center, D1-100, telephone: 206-667-6108.

After the award is made:
Pilot project reporting requirements:

(1) Eight weeks before the end of the annual funding period, Pilot project investigators will be required to submit a 3 page written progress report. This written progress report will serve as the competitive application for a potential second year of funding.

(2) Pilot Project award recipients will be required to present an oral report on the progress of the pilot projects at the FHCRC/UW CMCR Scientific Advisory Committee meeting every 6 months.

(3) Final Report will be required 10 months after completion of the Pilot Project, and will contain information on further progress of the studies initiated by the pilot funding, and acquisition of new independent external funding.

Monitoring success of pilot project programs. As a result of the research activity fostered by the pilot project, the FHCRC/UW CMCR hopes to successfully establish new areas of research activity to develop medical countermeasures against radiation. The FHCRC/UW CMCR Pilot Project Committee will evaluate progress in the pilot projects. A pilot project will be evaluated as successful if it generates data that has very strong evidence to develop into a product for medical countermeasures against radiation. With NIAID approval, successful pilot research projects may mature and become full research/development projects. If a pilot project is not deemed successful, it will not be funded for a second year.

The pilot proposals should represent a new project or new research direction for the principal investigator, and one that is likely to provide preliminary data to seek outside funding. Grants from more established investigators (e.g., Full Members or Professors) are only likely to be competitive if they are for a pilot study that is needed to establish a new direction and/or research project, rather than a project that is an extension of ongoing well-established studies. We are particularly interested in new projects that forge new collaborations between investigators in different disciplines.

Application for 2005 Pilot Fund Awards from FHCRC/UW Center for Medical Countermeasures Against Radiation

Project Title:

Key Personnel *(Please include an NIH Biosketch with a complete, updated active and pending other funding support for each individual)*

Name	Professional Title	Role on Project	Institution
		PI	

e-mail address and telephone number (with area code) for PI:

Does this study involve human subjects? (Y/N) Animals? (Y/N)
(If yes, IRB and/or animal committee approval must be obtained if this grant is awarded)

ABSTRACT *(200 words or less)*

Research Plan *(2 page maximum)*

Figures and Tables *(one page maximum)*

References *(one page maximum)*

Budget and Justification *(one page maximum)*

BIOSKETCHES FOR KEY PERSONNEL

Include biosketches for all key personnel involved with the pilot project, using the NIH PHS 398 biosketch format. Please provide a complete, accurate and updated other funding support documentation including active and pending support.