

CENTERS FOR MEDICAL COUNTERMEASURES AGAINST RADIATION: REQUEST FOR INFORMATION (RFI)

RELEASE DATE:

NOTICE: NOT-AI-04-027

RESPONSE DUE DATE: June 1, 2004

National Institute of Allergy and Infectious Diseases (NIAID) (<http://www.nih.niaid.gov>)

The National Institute of Allergy and Infectious Diseases (NIAID) of the National Institutes of Health (NIH) is planning to establish a network of Centers for Medical Countermeasures Against Radiation (CMCR) using the cooperative agreement (U19) mechanism. This program is part of a larger national plan to develop effective medical products to prevent and treat injury resulting from radiation after terrorist attack or accidental exposure to radiological or nuclear materials. The proposed network would support individual multi-project research centers conducting cross-disciplinary work in a variety of areas relevant to radiobiology and radiation epidemiology. In October 2004, the NIAID plans to issue a Request for Applications to establish these centers, with a receipt date for applications in February 2005, and an anticipated award date in September 2005.

Growing terrorist threats have highlighted gaps in the research and development of medical countermeasures for protection of the US civilian population against radiation. Few products are currently available for prevention of radiation injury, for treatment of post-exposure injury, or for the rapid identification of exposed individuals requiring treatment. Through this Request for Information (RFI), the NIAID would like to obtain information that is relevant to establishing the CMCR program, and to identify interested sources that are already developing products or research in this area, or that could facilitate the CMCR program and aid in the planning of this new initiative.

This RFI is for information and planning purposes only and should not be construed as a solicitation or as an obligation on the part of the Government. The Government does not intend to award a cooperative agreement on the basis of responses to this RFI nor otherwise pay for the preparation of any information submitted or for the Government's use of such information.

Background

There is an immediate need to develop new products for the biological measurement, prevention, and treatment of radiation injury caused by different levels of exposure to varied subsets of the civilian population, including healthy adults, pregnant women, young children, the elderly, and the chronically ill. The intent of the proposed CMCR program is to support multidisciplinary research groups or consortia at academic, commercial, or government institutions, providing core resources and new infrastructure where feasible, as well as support within each center for basic and translational research projects, relevant drug screen assay development, animal model development, and multidisciplinary training programs. The network of centers will be managed by a central steering committee to facilitate synergistic interactions and rapid progress towards new product development. Research results will be available to the general research community, as outlined in the current NIH policy on data sharing, to further facilitate rapid progress.

Examples of research areas for the CMCR include:

1. automated biology-based diagnostic assays/dosimeters for ready measurement of radiation injury;
2. radioprotectant and post-exposure therapeutic drugs or combinations of drugs;
3. therapeutic antibiotic or probiotic regimens;
4. innate and adaptive immune enhancement/reconstitution protocols;
5. hematopoietic stem cell expansion and storage for immune reconstitution;
6. stem cell expansion for mitigation of late organ toxicity;

7. mechanisms of radiation injury and host response;
8. rapid drug-screening assays to identify radioprotectants and radiotherapeutics;
9. small and large animal model development; and
10. long-term medical effects.

The NIAID is planning to use a cooperative agreement (U19) mechanism to establish 3-5 centers in FY 2005 and 2-3 centers in FY 2007. Modest planning grants (P20) will also be available in FY 2005 for groups needing support to coordinate research programs that will be competitive for FY 2007 U19 awards.

Information Requested

Information in the following areas will aid the NIAID in the design of the announcement for CMCR centers and planning grants. We ask interested organizations to identify critical criteria that should be included in the announcement, and to describe their interests as well as their current and potential capabilities to meet these criteria. Information need not be limited to these areas. Single institutions or consortia may be considered. Academic, government, and commercial groups are encouraged to respond.

Please restrict your response to 10 pages or less. Longer responses might not be evaluated.

1. Research areas

- a. Describe your interest and scientific capability to conduct basic and/or translational research in any of the areas listed above, or in additional areas relevant to radiobiology/radiation epidemiology. Prior work and current technical capabilities of personnel may be described.
- b. Describe your interest and scientific capability to develop or improve animal models for radiobiology research or to test candidate compounds for IND development and FDA approvals.
- c. Describe the criteria by which you would judge the usefulness of a research project, product candidate, drug-screening assay, or new animal model.
- d. Describe how a center should prioritize and coordinate its research program; and how a steering committee should operate to facilitate synergy and rapid progress.

2. Equipment/Techniques

- a. Describe your current facilities and equipment, and discuss the range of reagents, assays, animal models, techniques, and technologies available.
- b. Describe the core facilities you would need to establish or expand to conduct a comprehensive center program.

3. Multidisciplinary Training

Describe your capacity for a cross-disciplinary training program in radiobiology/radiation epidemiology. Include information on laboratory training and formal coursework, as well as appropriate teaching staff, potential applicants at the pre- and post-doctoral levels, and future potential to expand the program.

4. Infrastructure

Describe additional research resources you would need, including physical facilities, animal isolation units, large equipment, administrative support, and other infrastructure requirements.

Responses

Responses should be identified with this Notice identifier (NOT-AI-04-027), and are due by June 1, 2004. Please submit three (3) copies of your written response to:

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E-mail responses will also be accepted.

Acknowledgement of receipt of responses will not be made, nor will respondents be notified of the Government's assessment of the information received. However, should such an announcement materialize, no basis for claims against the Government shall arise as a result of a response to this request for information or the Government's use of such information as either part of our evaluation process or in developing specifications for any subsequent announcement. Responses will be held in a confidential manner. Any proprietary information should be so marked.