Office of Science Notice 99-05

Low Dose Research Program Scientific, Regulatory, and Societal Issues

Department of Energy Office of Science

Office of Science Financial Assistance Program Notice 99-05: Low Dose Research Program - Scientific, Regulatory, and Societal Issues

Agency: U.S. Department of Energy

Action: Notice inviting grant applications.

SUMMARY: The Office of Biological and Environmental Research (OBER) of the Office of Science (SC), U.S. Department of Energy (DOE), hereby announces its interest in receiving applications to address, analyze, and anticipate scientific, regulatory, and societal issues and opportunities arising from advances in low dose research and from current and planned regulatory policy. This may include research to summarize (1) the state-of-the-art of low dose research, (2) research and technology developments that support needs of the low dose research program, and (3) information needs and risk policy development strategies of regulatory agencies responsible for developing low dose radiation exposure standards. Research summaries should be submitted for publication in the peer-reviewed literature so they are broadly available to scientists, regulators, and the public. Information can be made broadly available through the development and use of a web site or other educational materials. Applications can also include the organization of studies, conferences, or workshops that identify and clarify, on an ongoing basis, the most urgent issues for the low dose research program and for the use of information developed in the program for risk assessment.

DATES: Potential applicants are encouraged to submit a brief preapplication. All preapplications, referencing Program Notice 99-05, should be received by DOE by 4:30 P.M. E.S.T., December 14, 1998. A response to the preapplications discussing the potential program relevance of a formal application generally will be communicated within 7 days of receipt.

The deadline for receipt of formal applications is 4:30 P.M., E.S.T., January 18, 1999, in order to be accepted for merit review and to permit timely consideration for award in FY 1999.

ADDRESS: Preapplications, referencing Program Notice 99-05, should be sent by Email to joanne.corcoran@oer.doe.gov; however, preapplications will also be accepted if mailed to the following address: Ms. Joanne Corcoran, Office of Biological and Environmental Research, SC-72, U.S. Department of Energy, 19901 Germantown Road, Germantown, MD 20874-1290.

Formal applications, referencing Program Notice 99-05, should be sent to: U.S. Department of Energy, Office of Science, Grants and Contracts Division, SC-64, 19901 Germantown Road, Germantown, MD 20874-1290, ATTN: Program Notice 99-05. This address must be used when submitting applications by U.S. Postal Service Express, any commercial mail delivery service, or when hand carried by the applicant.

FOR FURTHER INFORMATION CONTACT: Dr. David Thomassen, telephone: (301) 903-9817, Office of Biological and Environmental Research, SC-72, U.S. Department of Energy, 19901 Germantown Road, Germantown, MD 20874-1290. The full text of Program Notice 99-05 is available via the Internet using the following web site address: *http://www.er.doe.gov/production/grants/grants.html*.

SUPPLEMENTARY INFORMATION:

Background

Current standards for occupational and residential exposures to radiation and chemicals are based on linear, no-threshold models of risk that drive regulatory decisions and estimations of cancer risk. Linear, no-threshold models assume that risk is always proportional to dose, that there is no risk only when there is no dose, and that even a single molecule or radiation induced ionization can cause cancer or disease. However, the scientific basis for these assumptions is limited and uncertain at very low doses and dose rates.

Much scientific evidence suggests that the risks from exposure to low doses or low dose-rates of radiation and chemicals may be better described by a non-linear, dose-response relationship. This evidence includes long term human and animal studies and research at the cellular and molecular level on the DNA repair capabilities of cells and tissues, 'bystander' effects associated with low dose exposures, the effects of exposure-induced gene expression, the effects of a cell's micro environment on its response to low dose exposures, and studies of the multi-step nature of cancer development. A more definitive understanding of the biological responses induced by

low dose, low dose-rate exposures is needed to clarify the role played by these and other cell responses and capabilities in determining risk.

The low dose research program focuses on quantifying and understanding the mechanisms of molecular and cellular responses to low dose, low dose-rate exposures to radiation to improve the scientific underpinning for estimating risks from these exposures. The goal of this research program is the development of scientifically defensible tools and approaches for determining risk that are widely used, accepted, and understood.

Applicant Qualifications and Capabilities

Applicants should demonstrate knowledge of radiation biology, relevant literature, risk modeling strategies and needs, federal regulatory policy and policy development, and public concerns over exposure to radiation. Applicants should demonstrate their understanding of the needs for and the uses of the types of scientific information likely to be developed in the low dose research program. They should demonstrate understanding of previous epidemiologic and experimental studies involving low dose, low dose-rate exposures to radiation. Finally, interested applicants should demonstrate knowledgeability of research opportunities and capabilities at National Laboratories, universities, and industry in the area of molecular and cellular responses to low dose, low dose-rate exposures.

Program Funding

It is anticipated that up to \$300,000 will be available for grant awards during FY 1999, contingent on availability of appropriated funds. Multiple year funding is expected, contingent on availability of appropriated funds, progress of research, and programmatic needs. It is anticipated that a single award will be made.

Preapplications

A brief preapplication may be submitted. The preapplication should identify on the cover sheet the institution, Principal Investigator name, address, telephone, fax and E-mail address, title of the project, and the field of scientific research. The preapplication should consist of a two to three page narrative describing the research project objectives and methods of accomplishment. These will be reviewed relative to the scope and research needs of the DOE Low Dose Research Program.

Preapplications are strongly encouraged but not required prior to submission of a full application. Please note that notification of a successful preapplication is not an indication that an award will be made in response to the formal application.

Applications will be subjected to scientific merit review (peer review) and will be evaluated against the following evaluation criteria listed in descending order of importance as codified at 10 CFR 605.10(d):

- 1. Scientific and/or Technical Merit of the Project,
- 2. Appropriateness of the Proposed Method or Approach,
- 3. Competency of Applicant's Personnel and Adequacy of Proposed Resources,
- 4. Reasonableness and Appropriateness of the Proposed Budget.

The evaluation will include program policy factors such as the relevance of the proposed research to the terms of the announcement and an agency's programmatic needs. Note, external peer reviewers are selected with regard to both their scientific expertise and the absence of conflict-of-interest issues. Non-federal reviewers may be used, and submission of an application constitutes agreement that this is acceptable to the investigator(s) and the submitting institution.

Information about the development and submission of applications, eligibility, limitations, evaluation, selection process, and other policies and procedures may be found in 10 CFR Part 605, and in the Application Guide for the Office of Science Financial Assistance Program. Electronic access to the Guide and required forms is made available via the World Wide Web at:

http://www.er.doe.gov/production/grants/grants.html. The Project Description must be 25 pages or less, exclusive of attachments. The application must contain an abstract or project summary, letters of intent from collaborators, and short curriculum vitaes consistent with NIH guidelines.

The Office of Science, as part of its grant regulations, requires at 10 CFR 605.11(b) that a recipient receiving a grant to perform research involving recombinant DNA molecules and/or organisms and viruses containing recombinant DNA molecules shall comply with the National Institutes of Health "Guidelines for Research Involving Recombinant DNA Molecules", which is available via the world wide web at: *http://www.niehs.nih.gov/odhsb/biosafe/nih/nih97-1.html*, (59 FR 34496, July 5, 1994), or such later revision of those guidelines as may be published in the Federal Register.

The Catalog of Federal Domestic Assistance Number for this program is 81.049, and the solicitation control number is ERFAP 10 CFR Part 605.

John Rodney Clark Associate Director of Science for Resource Management Published in the Federal Register November 27, 1998, Volume 63, Number 228, Pages 65574-65575.