

DEPARTMENT OF VETERANS AFFAIRS Veterans Health Administration Washington DC 20420

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April xx, 2004

OFFICE OF RESEARCH AND DEVELOPMENT INFORMATION LETTER

REQUEST FOR APPLICATIONS ON GULF WAR VETERANS RESEARCH

1. Purpose

The Office of Research and Development (ORD) places a high priority on scientific research focused on further understanding the unexplained illnesses affecting veterans of the 1990-91 Gulf War. Research focused on the illnesses resulting from deployment to the Persian Gulf is currently funded through established programs that solicit investigator-initiated research, such as Merit Review, the Deployment Health Research Initiative, training programs (e.g., Career Development), and other programs including Cooperative Studies and Research Enhancement Awards. This Request for Applications (RFA) is a special opportunity to obtain research support for studies directly relevant to veterans who were deployed during the 1990's to the Persian Gulf. Applications may propose fully developed research studies that focus on potential long-term health effects of exposures and risk factors among veterans of the Gulf War in several areas of interest. Additionally, this RFA also offers an opportunity to propose innovative pilot projects focused on these topics.

- **2.** <u>Background</u>. Acute and chronic medical conditions result from deployment of troops to foreign lands in the course of military action. This RFA is specifically dedicated to supporting research to further understand the adverse physiological consequences resulting from deployment to the Persian Gulf. We are particularly interested in studies in the following areas:
 - Immunological changes (activation, suppression, interactions) that may be associated with the unexplained illnesses reported by Gulf War veterans
 - Autonomic system changes that may be associated with symptoms reported by Gulf War veterans
 - The prevalence of neurological disorders in Gulf War veterans

Proposals that address other important objectives regarding causes, mechanisms, and treatments for Gulf War veterans' illnesses will also be considered.

3. <u>Eligibility.</u> VA clinician and non-clinician scientists currently eligible to apply for research funding from any of the four ORD Services (Biomedical Laboratory, Clinical Science, Health Services, Rehabilitation Research and Development) may submit an application under this RFA. Principal Investigators with other VA funding, including

Merit Review funded by any of the ORD Services, are eligible to apply to this program; funding under this RFA would be in addition to the "single Merit Review rule" in Biomedical and Clinical R&D Services.

An approved Letter of Intent (LOI) is required to submit an application. LOIs will be reviewed for relevance to this specific RFA. Eligible applicants must submit a LOI in the following format:

- a. VHA LOI Cover (VA Form 10-1313-13)

 (available at http://www.va.gov/resdev/fr/forms.cfm)
- b. LOI text. Succinctly address each of the following (limited to two pages):
 - (1) Hypothesis(es)/Research Questions
 - (2) Discrete Study Objectives
 - (3) Description of Relevance to this RFA
 - (4) Overview of Design/Methods
 - (5) Description of Intervention(s)/Treatment(s) if applicable
 - (6) Total Budget and Study Duration
 - (7) Statement of Disclosure 1-2 sentence statement from the PI indicating that no financial or contractual relationship exists between any organization involved in the proposed study that could constitute a real or apparent conflict of interest (including all investigators and collaborators who plan to devote 5 percent or more effort to the proposed project). If such a relationship or contract does exist, full disclosure must be provided.
- c. Acknowledgment of the VA policy to include women and minorities in clinical research (if applicable).
- d. Up to five references.

4. Application Preparation and Submission.

Only applicants with an approved LOI may submit a full research proposal. Proposal preparation and submission guidelines should follow that of a Merit Review proposal as specified in the following Handbook:

http://www1.va.gov/resdev/directive/1202 Merit Review Handbook JIT.doc

Pilot projects that will approach existing problems from a new perspective and/or use new avenues of investigation will also be reviewed for funding. These pilot projects differ from traditional merit review proposals in that preliminary data, while useful, is not required. However, these pilot proposals should be based on a rational hypothesis derived from critical review and analysis of the literature and/or logical reasoning.

This is a special, one-time RFA. LOIs must be received by May 24, 2004. Research applications must be received by June 25, 2004. Review of proposals will take place in July/August 2004. Applications will not be reviewed if they are not submitted in accordance with the described procedures.

Letters of Intent should be sent to:

Department of Veterans Affairs (121E) Attn: Gulf War RFA 810 Vermont Avenue N.W. Washington, DC 20420

Applications should be sent to:

Department of Veterans Affairs (121F) Attn: Gulf War RFA 810 Vermont Avenue N.W. Washington, DC 20420

- **5.** <u>Review.</u> A specially convened committee comprised of scientific experts will review proposals. Proposals will be evaluated on the basis of scientific quality, significance and innovation of the research question(s), rigor of the methodological approach, feasibility, and relevance to this announcement requesting applications for research on Gulf War Veterans illnesses.
- **6. <u>Funding.</u>** Proposals may request up to three years of funding. The maximum budget for research studies will be \$150,000 per year, exclusive of Principal Investigator's (PI) salary. If a PI is eligible to receive a salary, the salary may only be included on the application if they are not already salaried from another VA source. The maximum budget for pilot projects will be \$100,000 per year, with a total duration of two years. The research design is expected to be appropriate and efficient, with all budget categories well justified. In planning project budgets, applicants are reminded to adhere to ORD guidelines regarding allowable use of research funds for specific items. Requests to exceed the budget may be included in the Letter of Intent.
- **7.** <u>Inquiries.</u> Please direct all questions regarding this RFA including questions about areas of research investigation, eligibility, application preparation, funding, and review to: Terri Gleason, Ph.D., (202) 254-0498 or Theresa.Gleason@hg.med.va.gov

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