



New Significant Funding Opportunity for Mesothelioma Research Investigators DOD Peer Reviewed Medical Research Program

The Mesothelioma Applied Research Foundation (Meso Foundation) is pleased to provide background information for investigators interested in pursuing research funding under the Department of Defense (DOD) Peer Reviewed Medical Research Program (PRMRP) in 2008.

A top priority for the Meso Foundation has been to strengthen the federal government's response to the mesothelioma tragedy through a commitment of new federal research dollars. Our advocacy efforts have finally paid off. In 2008, for the first time, mesothelioma will be included as a research priority within the DOD PRMRP. Mesothelioma investigators are now eligible to compete for funding through the program's 2008 grant cycle.

This funding opportunity can serve as a vital resource to our community and help advance the research and treatment of mesothelioma. The Meso Foundation strongly encourages mesothelioma investigators to consider submitting applications for funding in 2008. The interest and engagement shown by the community will likely be a factor in whether mesothelioma is included as a candidate in future years.

We hope the following information clarifies questions you might have on eligibility, timing and the PRMRP application review process. Specific information on the 2008 grant cycle is expected to be released in February. To receive an email notification informing you when specific information pertaining to the 2008 grant cycle is available, send an email to info@curemeso.org.

PRMRP Review Criteria—Understanding “Military Relevance”

Congress directs the DoD to “select medical research projects of clear scientific merit and direct relevance to military health.” We have found that this language is interpreted broadly.

The PRMRP itself defines military relevance as research that is “responsive to the health care needs of the Armed Forces, family members of the Armed Forces, and the U.S. Veteran population.” (Broad Agency Announcement (BAA) 05-1, DOD Peer Reviewed Medical Research Program, Fiscal Year 2006, accessed at <http://cdmnp.army.mil/funding/prmrparchive.htm>)

The PRMRP application process is conducted according to a two-tier review model recommended by the National Academy of Sciences, comprised of peer and programmatic reviews. Military relevance is a key feature of the Investigator-Initiated award and proposals must clearly explain the military relevance of the proposed research. A search of previously funded projects, and a review of their claims of military relevance, affirms that establishing this connection will not be difficult for mesothelioma investigators. The following section provides guidance and suggestions on demonstrating military relevance in your

application.

Tips on Demonstrating Military Relevance

Previously funded research varies significantly in the degree to which projects relate, serve or involve the military and veteran communities. There are projects with direct relevance to the active combat soldier including research on army nutrition, traumatic head injury, and Post Traumatic Stress Disorders among other topics. However, there are also projects with less direct relevance to the military, including disease-focused research on smoking cessation, breast cancer, childhood asthma, and myeloma, for example.

A search of previously funded cancer-related research identified seven projects funded between the years 2001 and 2005. Four of these studies focused on improving early detection and screening of breast, lung and cervical cancers. The stated military relevance of some of the projects was fairly minimal. For instance, in 2004, an investigator from the Southwest Research Institute was awarded a \$1.5 million grant through the Investigator-Initiated mechanism for a study on targeted therapies for myeloma and metastatic bone cancers. In the technical abstract, the authors suggested that the military population may be at a higher risk of developing bone cancer compared to the general population, due to potential exposure to agents used in warfare (such as depleted uranium and tungsten from munitions) that may increase the risk of various cancers.

Another study investigating the role of Do Tau mutations in increasing the susceptibility to amyotrophic lateral sclerosis (ALS), funded at just under \$1 million in 2005, noted that the incidence of ALS is increasing in Gulf War veterans. A project on childhood asthma, funded in 2001 under the Investigator-Initiated research award for \$899,000, simply stated that asthma is the “most common reason for hospitalization of children in both military and civilian hospitals.” And, that the “incidence of asthma is rapidly increasing in civilian and military children.” In essence, there was nothing that distinguished the military.

A complete search of previously funded research can be found at the website for the DOD PRMRP at <http://cdmrp.army.mil/scripts/search.asp>. The Meso Foundation can also provide summaries and technical abstracts of interest to mesothelioma investigators applying for funds under this program.

While we strongly encourage investigators to make as strong of a military connection as possible, the examples above show that establishing acceptable levels of military relevance can be done relatively easily and creatively. You might consider including the following references:

- There is an established history of asbestos exposure in military service, and elevated risk of mesothelioma in the military population. In fact, approximately one third of mesothelioma cases have been shown to involve Navy or shipyard exposures. (Butnor, Sharma, Sporn, Roggli: Malignant mesothelioma and occupational exposure to asbestos: an analysis of 1445 cases. *Ann Occup Hyg* 2002; 46: 150-153.)
- Reinforce that the military and veteran populations are at higher risk of developing mesothelioma due

to service related exposures to asbestos. Given the long latency of the disease, even if exposures are reduced, mesothelioma will continue to affect the veteran and military population for decades to come.

- Collaborate and integrate your project with military and/or Veterans Affairs (VA) research laboratories and hospitals. Please note that it is strongly encouraged that you include letters of support and verification letter(s) if your submission includes the involvement of military recruits or subjects, military-controlled study materials, databases, and/or restricted facilities.

If you need additional information on criteria for demonstrating military relevance, please contact the Meso Foundation directly at (805) 456-7273.

Award Mechanisms

In the past funding cycles, proposals were requested through five award mechanisms, although historically the number of submissions of the Investigator-Initiated Research Project Award has far exceeded the other types of awards:

- Investigator-Initiated Awards: *To encourage basic or clinical military-relevant health research in response to one of the topic areas eligible to compete for PRMRP funding.*
- Translational Research Award: *To support translational research focused on a health-related central problem or question. Translational research may be defined as an integration of basic science and clinical observations.*
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- Advanced Technology/Therapeutic Development Award: *The intent of this award is to provide support for the translation of promising preclinical findings into products for clinical applications. The products to be developed may be pharmacologic agents (drugs or biologicals), devices, or clinical guidance.*
- Clinical Trial Award: This award supports rapid implementation of clinical trials of interventions with the potential to have a significant impact on a disease or condition addressed in one of the FY08 PRMRP topic areas. The clinical trial may be designed to evaluate a pharmacologic agent (drug or biologic), device, or behavioral intervention.

General Budget Guidelines, Funding History and Timeline

The budget for the PRMRP is determined on an annual basis, depending on the appropriation provided by Congress. For FY 2006, \$50 million was allocated for this program. In FY 2007, Congress failed to approve any funding for the program. It has been announced that \$50 million dollars have been allocated for the program for FY 2008. There has yet to be a detailed program announcement for 2008, but when this is made, precise budget allocation for the awards will be outlined. This detailed program announcement will be made at <http://cdmnp.army.mil/>. Please check the program announcements and the “What’s New” column to stay up to date on the program’s time line. To serve as an example, however, the following are the budgetary guidelines for 2006. Please note that the maximum direct costs can be

requested over the performance period, which can extend up to 4 years.

| Award Mechanism | Direct Cost (Maximum) | Performance Period (Maximum) |
|------------------------------------|------------------------------|-------------------------------------|
| Investigator-Initiated | \$625,000 | 4 Years |
| New Program Project | \$1.25 million | 4 Years |
| Existing Program Project | \$1.25 million | 4 Years |
| Adv. Tech.: Project/Technology | \$940,000 | 4 Years |
| Adv. Tech: Clinical Testing/Trials | \$2.5 million | 4 Years |

In recent years, applicants have been asked to provide letters of intent in March or April of the application year. Deadline for the submission of full proposals has generally fallen in May; however, timing on the letters of intent and proposals has varied from year to year. The peer review process has generally commenced in early to late summer, with awards made in mid-Fall. Please stay posted for up-to-date information on the 2008 application cycle.

Commonly Made Mistakes

- Not obtaining or confirming the organization's DUNS number well before the proposal submission deadline.
- Not obtaining or confirming the organization's registration with the Central Contractor Registry (CCR) well before the proposal submission deadline.
- Failing to request "send me change notification emails" from Grants.gov.
- Not contacting HELP DESKS until just before or after deadlines.
- Not completing the pre-application submission before the mandatory pre-application deadline (pre-application remains in draft status).
- Using an incorrect Grants.gov application package to submit a proposal through Grants.gov. Each Program Announcement/Funding Opportunity requires a specific application package.
- Uploading attachments into incorrect Grants.gov forms.
- Attaching files in the wrong location on Grants.gov forms.
- Submitting attachments that are not PDF documents, except for the R&R Subaward Budget Attachment(s) Form.
- Exceeding page limitations.
- Failing to submit a proposal 48-72 hours before the deadline so that Grants.gov can provide notification of errors and allow for resubmission of application package.
- Failing to submit proposal by submission deadline.

General Information for Applicants Submitting Proposals

- Proposals are being solicited from agencies of local, state and Federal governments, educational institutions, nonprofit organizations and private industry.

- All proposals and supporting documentation must be submitted electronically. No paper copies will be accepted.
- Applicants are expected to survey the peer-reviewed literature to avoid duplication of previously described research efforts, including those previously supported by the DOD and/or its investigators. Information on previously accomplished research supported by the DOD can be found at the Defense Technical Information Center website at <http://www.dtic.mil>.
- Proposals must be submitted to <http://cdmrp.org> by the specified deadline. The deadline is considered extremely rigid and applications submitted even minutes after the deadline are not accepted.

Additional Sources of Information

- For all information, forms, documents, and links needed to apply, interested applicants should go to <http://cdmrp.org>.
- For information on former PRMRP participants, go to <http://cdmrp.army.mil/prmrp/peerreviewers.htm>.
- Information about previously funded research under the Congressionally Directed Medical Research Program may be obtained by searching the program's online database at <http://cdmrp.army.mil/scripts/search.asp>.
- To be added to the mailing list for notification of funding opportunities and program announcements for 2008, email prequest@constellagroup.com.
- The PRMRP maintains a variety of contacts to answer questions related to the program, proposal format or required documentation.

Questions Concerning the CDMRP:

Phone: (301) 619-7071

Proposal Inquiries:

U.S. Army Medical Research and Materiel Command
ATTN: MCMR-ZB-C
1077 Patchel Street
Fort Detrick, MD 21702-5024

Questions Concerning Proposal Requirements:

Phone: (301) 619-7079
Fax: (301) 619-7792
E-mail: cdmrp.pa@det.amedd.army.mil

Mailing List for Funding Opportunity Notifications:

E-mail: Help@cdmrp.org

Questions Concerning Consumer Involvement:

ATTN: Consumer Recruitment
1077 Patchel Street
Fort Detrick, MD 21702-5024
Phone: 301-619-7079
Fax: 301-619-7792
E-Mail: cdmrp.consumers@det.amedd.army.mil