

Supplement to the U.S. Army Medical Research Materiel Command Broad Agency Announcement (BAA) 04-1: Candidate technologies for advanced first- responder resuscitation fluid (AFRRF)

SUBJECT: The purpose of this announcement is to request pre-proposals regarding candidate technologies/products for fluid resuscitation that can be used by first responders and combat medics to resuscitate wounded military personnel on the battlefield.

DESCRIPTION: The U.S. Army Medical Research and Materiel Command (Fort Detrick, MD), in cooperation with the U.S. Office of Naval Research (Arlington, VA), seeks research on candidate technologies-products that can potentially be applied to development of a resuscitation fluid(s) or resuscitation fluid adjunct(s) that can be readily and easily administered by first responders and combat medics on the battlefield. By 2020, or earlier, the Army, the Navy, and the Department of Defense (DoD) seek to significantly reduce the number of casualties who are killed-in-action (KIA, expire before reaching a medical treatment facility) by providing improved, more effective fluid resuscitation earlier after the wounding event. A secondary goal is to substantially mitigate post-wounding and post-resuscitation morbidity.

Respondents are encouraged to provide information about fluid resuscitation technologies-products that potentially can be or have been demonstrated to be effective in treating blood loss and shock, preventing complications, and improving chances for survival.

Responses will be compiled by the Life Sciences Research Office (LSRO) in consultation with an Expert Panel, which has been engaged to conduct an independent review and prioritize candidate technologies/products. Full proposals will be requested for technologies deemed to be of interest and applicable to our goals.

FUNDING AVAILABLE FOR AWARD: Technologies selected for collaboration and continued development by the DoD will be eligible for extramural (or any combination of extramural and intramural collaboration) awards of \$100K to \$500K for pre-clinical studies and up to \$1M for early (Phase 1 or Phase 2) clinical studies. Total available funding for all awards is approximately \$4 million per year until 2010. Awards may be in the form of assistance agreements (grants or cooperative agreements) or contracts.

PRODUCT REQUIREMENTS: The military is open to alternatives to standard solutions that can be used to treat volume deficits resulting from blood loss in far forward deployment areas. Hence, product requirements are based on logistical considerations of transport, storage, and utilization in combat field conditions as well as medical considerations. Products proposed in response to this request must meet one or more of these functional requirements:

- Fluid conservative treatment with hypotensive end-points
- Stable for prolonged periods at typical battlefield temperatures (less than or equal to 130 degrees F, including less than 32 degrees F)
- Provides supplemental oxygen-carrying capacity
- Mitigates or negates post-shock, post-resuscitation syndromes
- Compatible with blood products
- Easily and quickly administered by first-responder-medical personnel with limited training
- No mental or physical post-resuscitation impairment specific to the treatment

To the extent that simplifying assumptions about these product requirements are needed, respondents are encouraged to make and document such assumptions in their response.

RESPONSE OUTLINE

In lieu of a preproposal, this announcement requires responses that must contain the following information and data to the extent that they are available:

1. **Product description:** Briefly describe the candidate technology/product and whether the product is approved for other uses.
2. **Data:** Summarize the supporting in vivo, pre-clinical and clinical data that validate the benefits/utility of this product. Describe the mode of action. Please comment on any safety evaluations that have been conducted and additional studies underway or planned for the near-future.
3. **Implementation:** Discuss schedule considerations for how soon the product would be ready for human clinical trials and whether Phase III funding is available.
4. **Other:** Provide any other materials and discussion you deem appropriate, including your willingness to present information to the Expert Panel in the future.

Submissions will be evaluated in accordance with the criteria outlined in the Broad Agency Announcement 04-1 for at www.usamraa.army.mil under the BAA button.

Point of contact for inquires about response content and the LSRO project:

Dr. Catherine Klein
(301) 634-7032
kleinc@LSRO.org
www.LSRO.org

SUBMISSION OF INFORMATION: Responses are not limited by country of origin but must be in the English language. Only information contained in the first 5 pages of the response will be considered. LSRO endeavors to make the review process as public as possible; hence, non-proprietary information is preferred. However, LSRO has made provisions to handle confidential and proprietary information so that each page of response marked 'Proprietary' and-or 'Confidential' will be handled accordingly. Please provide the name and contact information of an individual who could respond to requests by LSRO for additional information.

Submissions in response to this announcement must be sent to the following address and must be received not later than 2 PM, **7 September 2004**. Submissions should consist of one hard copy and electronic files on a CD compatible at least with Windows 2000 or XP operating systems. Submissions received after this date will not be guaranteed a full review by LSRO.

Mail or courier submissions to:

USAMRAA
ATTN: MRMC-BAA-AFRRF
820 Chandler Street
Fort Detrick, MD 21702-5014