CounterACT Efficacy Research Facility (CERF)

The NIH NIAID Chemical Countermeasures Research Program (CCRP) includes a state-of-the-art facility to support the research and development of medical countermeasures for chemical threats. This facility is a NIH supported program called the CERF and is equipped to conduct exploratory and translational research on the efficacy of compounds against the lethal and non-lethal effects of chemical threat agents using new and established animal models.

A purpose of the CERF program is to assist applicants to obtain important proof-of-concept efficacy data, i.e., pilot studies, in support of a research application to the CounterACT peer-reviewed grant program. The proposed studies must not overlap with, but may be performed done in concert with studies conducted through other CCRP efficacy and preclinical support programs (e.g., CounterACT Preclinical Development Facility (CPDF) and CounterACT Neurotherapeutics Screening (CNS) program). If approved by NIH, studies are performed at no cost to the investigator. Participants will retain custody of and have primary rights to the data developed under these awards, subject to Government rights of access consistent with current HHS, PHS, and NIH policies.

Before, during, and subsequent to the award, the U.S. Government is not required to obtain for the participants any proprietary rights, including intellectual property rights, or any materials needed by the applicant to perform the project. Participants may wish to establish a separate Material Tech-Transfer/Lab Service Agreement with the CERF and/or the NIH.

* The CERF does **not** replace the need to formally establish (and budget for) collaboration with laboratories, such as the Department of Defense U.S. Army Medical Research Institute of Chemical Defense (USAMRICD) and others that are certified to work with restricted as well as unrestricted chemical agents within research applications submitted in response to NIH FOAs.

Eligibility Criteria:

NIH will accept applications from individual Principle Investigators (PIs) from academic institutions, government laboratories, and/or companies. PIs may consult with NIH to determine eligibility.

a) Non-domestic (non-U.S.) Entities (Foreign Institutions) are not eligible to apply.
b) Non-domestic (non-U.S.) components of U.S. Organizations are not eligible to apply.

Study Criteria:

1. These limited studies will facilitate characterization and optimization of hits and/or leads early in the development process.
2. Efficacy of the specifically proposed product must be demonstrated in at least one acceptable *in vitro* and/or *in vivo* (preferable) model prior to submission of the Product Development Pre-Proposal (PDP).
    - Efficacy of the specifically proposed product may be shown against the actual threat agent OR an acceptable surrogate agent within the same chemical class.

Procedures for Submitting Compounds to the CounterACT Efficacy Research Facility (CERF)

General Procedure:

1. NIH will accept PDPs from individual applicants within and outside of the CounterACT grant program with promising potential medical countermeasure(s) that would be responsive to the goal of the CCRP. Applicants may consult with NIH to determine eligibility and general efficacy needs.
2. Cover Letter
    a. Project Director/Principal Investigator (PD/PI) name
    b. Title of requested research effort
    c. Name, title of the authorized organizational representative (AOR)
    d. Phone, email, and address information for both the PD/PI and the institutional official.

    The cover letter must be signed by the AOR and PD/PI.
3. The PDP will be 3-5 pages. If they do not contain the following sections, they will be returned without further review:
    a. Introduction – Describe how these studies will advance the development of the candidate therapeutic. How will these studies serve as a go/no go point for further drug development?
    b. Justification – Describe any efficacy and preclinical (i.e., PK, safety, chemistry, etc.) studies and results that have already been completed on the specifically proposed product.
    c. Research Needs summarizing, in general, which research track is proposed in this pre-proposal, what type of work you are requesting, and specifics for the studies (i.e., required animal model, route of agent exposure, administration route of therapeutic, endpoints, etc.).
4. The NIH will begin accepting PDPs immediately, commencing December 1, 2010. There are no receipt deadlines.
5. PDPs will be reviewed by the CCRP within 3-4 weeks of receipt.
6. Review criteria include eligibility (e.g., previous efficacy data of the specifically proposed product), impact on the overall drug development process, programmatic priorities, and availability of NIH resources.
7. If the PDP is approved, the investigator **and** CERF study directors will prepare a full CERF Study Proposal (CSP) and budget for final review and approval by the NIH before the studies begin, no later than one month after initial approval of the PDP.
8. A final Technical Report (TR), including task background, objectives, assumptions, specific data collected, analyses conducted, conclusions and recommendations, will be delivered to the investigator by the NIH at the conclusion of the study.

Applicants are strongly encouraged to contact CCRP staff for further information.

Submit Pre-Proposals **by email** to:

Dave Yeung, Ph.D.
NIH/NIAID
Chemical Countermeasures Research Program (CCRP)
Tel: 301-761-7237
dy70v@nih.gov

NIH National Institutes of Health