

CounterACT Efficacy Research Facility

The NIH NIAID Chemical Countermeasures Research Program (CCRP) offers the CounterACT Efficacy Research Facility (CERF) program to support exploratory and translational research to evaluate the efficacy of potential medical countermeasures (MCMs) against chemical threat agents using new and established *in vitro* and *in vivo* models.

The proposed studies may not overlap with, but may be performed in concert with, studies conducted through other CCRP resources. The primary purpose of the CERF program is to provide applicants with proof-of-principle pilot efficacy data in support of follow-on research efforts. Studies approved by the CCRP are performed at *no cost* to the applicant.

The CERF does *not* replace the need to establish direct collaborations with laboratories that are certified to work with restricted and unrestricted chemical agents within follow-on research efforts.

All information provided to the NIH-supported laboratory will be treated as confidential. Participants will retain custody of and have primary rights to the data developed, subject to government rights of access consistent with current HHS, U.S. Public Health Service, and NIH policies.

Study Criteria

The limited pilot studies conducted under the CERF program aim to facilitate characterization and optimization of potential MCM compounds early in the development process. Efficacy of the proposed compound must be demonstrated in at least one acceptable *in vitro* and/or *in vivo* (preferable) model *prior* to submission of a study pre-proposal. Efficacy may be shown against the actual threat agent *or* an acceptable surrogate agent within the same chemical class.

Applicant Eligibility Criteria

In general, the CERF program is available to all investigators with promising MCMs responsive to the mission of the CCRP. NIH will accept applications from individual principal investigators (PIs) from academic institutions, government laboratories, and companies. PIs

Need pilot efficacy data for potential MCMs against chemical threats?

CERF
may be able to help.

from foreign institutions and non-U.S. components of U.S. organizations are *not* eligible to apply. Applicants may consult with NIH to determine eligibility.

Overview of the CERF Application Process

Each application must be accompanied by a cover letter. The study pre-proposal should not exceed five pages and must contain the following sections:

- **Introduction** providing background information about the compound
- **Justification** describing results from efficacy and preclinical (pharmacokinetics, safety, chemistry, etc.) studies that have already been completed
- **Explanation of Research Needs** providing a general summary of the type of work requested and specifics for the studies, such as required animal model, route of agent exposure, administration route of therapeutic, and endpoints

Please request a complete set of application instructions before preparing a study pre-proposal. There are no receipt deadlines. CCRP will review study pre-proposals within three to four weeks of receipt. 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.

If the study pre-proposal is approved, the applicant *and* CERF study director(s) will prepare a full statement of work (SOW) and estimated budget for final review and approval by NIH before the studies begin. Preparation of the SOW will begin no later than one month after initial approval of the pre-proposal.

NIH will deliver a final study report to the investigator at the end of the study.

Who To Contact

To learn more about the CERF or request preparation instructions for a study pre-proposal, please contact (preferably by email)

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Additional Information

NIH NIAID Chemical Countermeasures Research Program (CCRP)

<https://www.niaid.nih.gov/research/chemical-countermeasures-program>

NIH Countermeasures Against Chemical Threats Program (CounterACT)

<https://www.ninds.nih.gov/CounterACT>



National Institute of
Allergy and
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