



DEVELOPMENTAL GRANTS

Request for Applications Application Deadline: September 21, 2009

New England Regional Center of Excellence for Biodefense and Emerging Infectious Diseases Research

The New England Regional Center of Excellence for Biodefense and Emerging Infectious Diseases Research (NERCE) invites applications for funds under its *Developmental Grant* program. The objective of this program is to support innovative, cutting edge research in areas that may yield discoveries that would translate into the creation of new vaccines, therapeutics and/or diagnostics directed against biological agents that have been identified as having the potential to pose a severe threat to public health and safety.

Applications are due **September 21, 2009**. Awards will be made in **November 2009**.

NERCE (<http://nerce.med.harvard.edu>) is one of eleven Regional Centers of Excellence established by NIAID in September of 2003, as part of its biodefense research plan. NERCE was recently renewed to broadly support infectious disease research in New England through 2014. The program currently supports 13 projects focused on basic research and development of vaccines and therapeutics for the prevention and treatment of diseases resulting from infection by *Yersinia pestis*, *Francisella tularensis*, *Staphylococcus aureus*, Nipah virus and other pathogens (NIAID category A-C priority pathogens and emerging infectious diseases: <http://www3.niaid.nih.gov/topics/emerging/list.htm>). Investigators supported directly by NERCE are located at different institutions in New England, including Boston Medical Center, Boston University, Brigham and Women's Hospital, the Immune Disease Institute, Harvard Medical School, the University of Massachusetts Medical School, Tufts University and Children's Hospital, Boston.

NERCE maintains 4 core laboratories and resources to support each of the Center's research programs in areas such as high containment (BSL-3) microbiology and laboratory animal resources, high-throughput chemical screening, medicinal chemistry, biomolecule production, and live-cell imaging. As a regional center, these core laboratories and resources also support biodefense and emerging infectious diseases research efforts of other investigators from any of New England's academic institutions, research institutions, and biotech and pharmaceutical companies, regardless of the source of funding for these projects. Each of the core laboratories strives to provide its services with minimal, if any, cost to the investigator.

Objectives and Goals

The objectives of the *Developmental Grant* program are to:

- Promote innovative, cutting edge research that may yield discoveries that would translate into the creation of new vaccines, therapeutics and/or diagnostics to combat Category A-C select agents or other emerging infectious pathogens.
- Invest in research projects with the greatest potential to grow to full NERCE research programs or to projects that would be competitive for other NIH funding.
- Support “higher risk” research with less preliminary data.
- Attract investigators who are not working in the area of emerging infectious diseases to begin research programs on Category A-C agents and emerging pathogens.
- Attract investigators from institutions and companies that are not participating in the NERCE program.
- Encourage collaborations among investigators, particularly between basic and clinical research laboratories and between traditional microbiology laboratories and investigators in other basic science disciplines (e.g., immunologists, cell biologists, chemical biologists, bioinformaticists).

Key Elements of the Program

- **ELIGIBLE INVESTIGATORS AND PROJECTS:** Independent full time faculty members or employees of an academic, private, public or corporate entity in Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, or Vermont. First time investigators are encouraged to apply. Investigators who currently have direct NERCE funding are not eligible. Projects previously funded by NERCE are not eligible for additional funding, but investigators may apply for support of a new project.
- **DEFINITION OF DEVELOPMENTAL:** The intention of the *Developmental Grant* program is to support “higher risk” research; therefore less preliminary data are required when compared to conventional “R01”-like grants.
- **SCIENTIFIC AREA:** Each proposal should focus on one or more NIAID emerging and re-emerging Infectious Diseases (<http://www3.niaid.nih.gov/topics/emerging/default.htm>) or on a technology that has direct relevance to the development of vaccines, therapeutics, or diagnostics directed against these diseases.
- **FUNDING:** Three awards at \$125,000 per year (direct costs) will be awarded for a maximum of two years. Indirect costs will also be provided. Funding for the second year of all awards is contingent upon satisfactory progress as judged by the NERCE Scientific Steering Committee and program officers at NIAID, and upon continued NERCE funding by NIAID.
- **APPLICATION:** An abbreviated initial application based on the PHS 398 application materials will be used. Proposals selected for funding will be provided to NIAID Regional Centers of Excellence Program staff for final approval prior to preparation of awarding subcontracts between Harvard Medical School and the Principal Investigator’s home institution.

- **MONITORING:** The following items are required of all awardees of the *Developmental Grant* program:
 1. Progress report 3 months prior to the start of next year of funding;
 2. Final report due no later than 60 days from the end of the award period;
 3. Presentation at the NERCE Annual Retreat.

Application Process

The application must be submitted on PHS 398 application packet forms (<http://grants2.nih.gov/grants/funding/phs398/phs398.html#forms>) and include:

Form Page 1: Face Page – completed, but institutional signatures are **not** required at time of application;

Form Page 2: Description, Performance Sites, Key Personnel, and Significant Contributors;

Form Page 4: Detailed budget (\$125,000 maximum per year, plus Indirect Costs);

Form Page 5: Budget for entire 2-year period;

Biographical Sketch (parts A, B, and C, current support only) for each collaborating investigator (2 page maximum each);

Research Plan (3 pages maximum) including:

- A. Specific Aims;
- B. Background and Significance;
- C. Preliminary Studies, if any;
- D. Research Design and Methods;
- E. Literature citations.

Limit sections A-D of the research plan to 3 pages. Literature citations are not included in the 3-page limit. **Do not submit appendices.** Institutional signatures and PHS 398 checklist page are not required with initial application. These will be requested only if the application is chosen for funding. Applicants proposing use of or collaborations with any of the NERCE Core Laboratories must provide a letter of support from the PI or Assistant Director of the core.

Submission Instructions

- Applications must be received by **5:00 p.m., September 21, 2009.**
- E-mail applications as a **single** Word or PDF (preferred) file containing “Developmental” in the subject line to: NERCE@hms.harvard.edu

Selection Criteria and Process

Applications will be reviewed for programmatic and technical merit by the NERCE Scientific Steering Committee (SSC). This committee is composed of established scientists from throughout New England with expertise in infectious disease research. The SSC has primary responsibility for selecting the projects to be funded.

- Scientific Merit of the Proposal:
 - Clearly formulated specific aims based on existing scientific knowledge;
 - Experimental plan that will directly address specific aims;
 - Measurable results within the timeframe of the project; and
 - Potential for independent funding or NERCE research project status.

- Qualities of the Investigator:
 - Track record of successful scientific inquiry appropriate to current career stage;
 - Funding will broaden the institutional participation in NERCE;
 - Funding will promote career development and expertise of the investigator in biodefense research.
- Complementary to existing NERCE programs and resources:
 - Use of NERCE core facilities;
 - Use of NERCE expertise on committees and current investigators;
 - Synergistic with existing NERCE programs;
- Significance of proposal to contribute to national biodefense mission:
 - Program addresses needs described in the NIAID Emerging and Re-emerging Infectious Diseases site (<http://www3.niaid.nih.gov/topics/emerging/default.htm>);
 - Risk/Reward relationship;
 - Interdisciplinary approaches are used.

Preference will be given to scientists of regional institutions underrepresented in NERCE supported research. Selected applications must also be approved by NIAID Program Officers prior to award. Minorities, women, and individuals with disabilities are encouraged to apply. The Scientific Steering Committee members will not be able to provide formal written reviews for unfunded applications.

Additional Conditions of Award

Approvals and agreements will not be required for scientific review. However, if your application is selected for award, NERCE program management will require the following before issuing the award:

- 1) a signed PHS 398 form page 1 (Face page);
- 2) if applicable, IRB approval for human studies and PHS 398, section E;
- 3) if applicable, institutional approval for animal studies and PHS 398, section F;
- 4) PHS 398 checklist page;
- 5) Institutional Biosafety approval;
- 6) if applicable, inter-institutional agreements regarding intellectual property, data-rights and data sharing.

For further information please contact:

Lawrence C. Paoletti, Ph.D.
Assistant Director, Developmental Grants and NERCE Fellowship Programs
New England Regional Center of Excellence
Brigham and Women's Hospital, Channing Laboratory
221 Longwood Avenue
Boston, MA 02115
617-525-7878 (tel)
NERCE@hms.harvard.edu

Copies of this RFA may be found on the NERCE website at <http://nerce.med.harvard.edu>