



**NIH/NIAID Region V Great Lakes
Regional Center of Excellence for Biodefense and Emerging Infectious Diseases Research**
Request for Applications: Developmental Projects

RELEASE DATE: March 15, 2010

APPLICATION DUE DATE: August 2, 2010

PURPOSE OF THE RFA

The Great Lakes Regional Center of Excellence for Biodefense and Emerging Diseases Research (“GLRCE”) is one of eleven NIAID supported regional centers serving as an essential component of the governments plan for biodefense research, led by the University of Chicago.

The mission of the GLRCE is to develop novel vaccines, therapeutics and diagnostics to combat microbiological agents identified as having the potential to pose a severe threat to public health and safety. Of particular interest are those microbial agents with bioterrorism potential, designated the NIAID Category A, B and C Priority Pathogens and Emerging Infectious Disease Agents. A list of these pathogens can be found at <http://www.niaid.nih.gov/dmid/eid/erd.htm>.

The GLRCE Developmental Projects Program will support innovative research that has a high likelihood of yielding information leading to the development of new vaccines, therapeutics and/or diagnostics against these agents. Furthermore, results gained from the Developmental Projects Program are intended to support the acquisition of funding from traditional federal mechanisms (NIH R01, etc). Therefore, only a small amount of preliminary data is required for Developmental Projects thereby fostering the development of novel approaches towards the study of the mechanisms of infectious disease intervention and/or immunity to disease. Topics of interest to the GLRCE include, but are not limited to:

- Pathogen biology, including the identification and characterization of new virulence factors
- Bacterial toxins
- Host Immune response
- Microbial immune evasion and enhancement
- Animal models of infection and immunity
- Target identification for vaccines, therapeutics, adjuvants, and diagnostics;

Special consideration will be given to those projects with emphasis on discovery and early development of medical products.

PARTICIPATION IN THE GREAT LAKES REGIONAL CENTER OF EXCELLENCE

The GLRCE is a consortium based in the federally-designated “Region V” of the United States. Region V includes six states in the upper Midwest: Illinois, Indiana, Michigan, Minnesota, Ohio and Wisconsin. Currently, twenty six institutions in Region V are formally associated with the GLRCE (for a list of participating institutions, please refer to: <http://www.glrce.org>). For an investigator to be funded by the GLRCE, his/her institution must be a formal member of the consortium. Information regarding membership requirements can be found on our website.

RESEARCH CURRENTLY SUPPORTED BY THE GLRCE

The Great Lakes Regional Center of Excellence for Biodefense and Emerging Infectious Disease Research currently supports numerous projects focused on the molecular analysis and intervention of the following pathogens and toxins:

- *Bacillus anthracis*
- Botulinum neurotoxin
- *Yersinia pestis*
- Ebola virus
- Dengue hemorrhagic fever virus
- Smallpox
- Methicillin-resistant *Staphylococcus aureus*
- *Francisella tularensis*
- *Brucella melitensis*

RESOURCES OF THE GLRCE

To facilitate the research and training objectives of GLRCE investigators, the consortium also supports three research resources, including:

- Administrative Core
- Animal Research and Immunology Core (ARIC)
- BSL3 Training Curriculum
- **The Howard Taylor Ricketts Laboratory (HTRL)** provides a safe and secure facility for research on the prevention and treatment of infectious disease. Built and operated by the University of Chicago, it is sited on land owned by the U.S. Department of Energy at Argonne National Laboratory, southwest of Chicago. The HTRL construction project was funded primarily by the National Institute of Allergy and Infectious Disease (NIAID) with additional support from the State of Illinois and others. Risk group 2 laboratory area is 3,904 sf; Risk group 3 laboratory area is 3,627 sf; animal care/support is 10,707 sf.

In addition to these GLRCE research resources, the National RCE Biodefense Network supports an additional research resource that may be used by any GLRCE member:

- National Screening Laboratory for the Regional Centers of Excellence for Biodefense and Emerging Infectious Disease (NSRB) (<http://nerce.med.harvard.edu/core-smallmol.html>)

GLRCE DEVELOPMENTAL PROJECTS PROGRAM

Four new "DP" awards are expected to result from this solicitation, with funding to begin on or about March 1, 2011. Priority will be given to research involving the translation of basic science into therapeutic products as well as those applications with the greatest potential to assume further funding at the conclusion of the project (R01 proposal, etc.). Awards will be made for up to two years, with a maximum project budget of \$125,000 direct costs per year. The second year of funding is dependent upon satisfactory progress.

WHO CAN APPLY

Applications from faculty members within GLRCE member institutions are welcome. Interested researchers from institutions not yet members of the GLRCE may also apply. By the Executive Board review, all GLRCE investigators awarded must reside in institutions that formally belong to the GLRCE.

SUBMITTING AN APPLICATION

The initial application (due August 2, 2010) should utilize the latest PHS 398 **non-modular** application forms. Your proposal must be institutionally endorsed.

- Up to 5 pages of text including specific aims, background and significance, preliminary data, and research plan (sections a-d of PHS 398 forms). Copies of manuscripts in press may be included as appendices and will not count against the page limit.
- Human Subjects, Vertebrate Animals, Literature Cited and Consultants must be included but do not count against the page total.
- Letters of support for those proposals involving collaborations with other GLRCE scientists, GLRCE cores or components, members of other Centers or members of industry (as applicable).

PHS 398 forms may be found at: <http://grants.nih.gov/grants/funding/phs398/phs398.html>

RECEIPT AND REVIEW SCHEDULE

Applications must be received by 5:00 p.m. on Monday, August 2, 2010. For administrative purposes, please also e-mail the application as a Word file to Catherine Will at cwill@bsd.uchicago.edu. The GLRCE Executive Board Working Group and the GLRCE External Scientific Advisory Board will conduct review sessions of the Developmental Project Proposals to determine which applications may be considered for support. The Principal Investigator/investigators of such pre-selected proposals may submit an abstract on their application/research program for presentation at the GLRCE Annual Meeting (September 28-29, 2010 in Chicago). The NIAID will subsequently provide final approval for funding.

REVIEW CRITERIA

The criteria for selection used by the EB will include the following areas:

- *Scientific merit* - Clear specific aims with well-referenced body of text; innovation or originality of proposed work; potential problems addressed; defined milestones; potential for continued/outside funding;
- *Complementarity to existing GLRCE programs* - Project use or enhancement of existing GLRCE resources and research programs;
- *Complementarity to the GLRCE biodefense mission* - Does the project advance the long range plans of the GLRCE? Does the project contribute to product development for NIAID priority pathogens?
- *Past performance* of the Principal Investigator and co-investigators;
- *Environmental analysis*, including the institutional environment and its ability to provide the tools, equipment and research infrastructure to perform the proposed experiments.

FUNDS AVAILABLE

This solicitation will result in the recommendation of four Developmental Project applications to the NIAID for funding, to begin on or about March 1, 2010. Awards are granted for a maximum of \$125,000 in direct costs/year. Funding for the Development Projects Program is contingent on continued funding of the GLRCE by the NIAID. Developmental Projects are evaluated routinely and their continued funding is dependent on satisfactory progress as recommended by the GLRCE EB, and ESAB.

ADDITIONAL CONDITIONS OF AWARD

As appropriate, applications must include a complete Vertebrate Animals or Human Subjects Research Protection section, as described within the NIH PHS 398 grant application form instructions. If human subject research is involved, NIAID must be in receipt of the IRB approval letter, the IRB approved protocol, and the informed consent document component before the award will be made, or research may occur.

If the proposed research involves infectious agents, the application's Biohazard issues must be fully addressed. Where applicable, research questions that involve the molecular or infection biology of Category A-C Agents should be addressed with fully virulent, clinically relevant isolates not with attenuated strains. The feasibility of the proposed studies should therefore take into consideration the availability of protocols reviewed and approved by the Institutional Biosafety Committee (IBC) and the Institutional Animal Care and Use Committee (IACUC) of the applicant organization(s). Further, applications must include a description of laboratory safety and, where applicable, CDC Registration and Approval for facility and select agent operation.

The progress of all Developmental Projects will be closely monitored by the GLRCE Executive Board. Quarterly progress and financial reports must be submitted to the GLRCE Director on March 1, June 1 and September 1 of each year of funding. Fourth quarter progress reports will be in the form of the Annual GLRCE Renewal, and will likely be due on September 1, 2011 (and each additional year of funding). All investigators of GLRCE Developmental Projects are expected to present research progress at the annual GLRCE and National RCE meetings each year.

WHERE TO SEND INQUIRIES

Direct questions about scientific/research issues to:

Olaf Schneewind, MD, PhD

Director, GLRCE

NIH/NIAID Region V Great Lakes Regional Center of Excellence
for Biodefense and Emerging Infectious Diseases Research

University of Chicago

920 E. 58th St., Chicago, IL 60637

oschnee@bsd.uchicago.edu

Direct questions about financial or grants management matters to:

Catherine Will, CRA

Grants and Contracts Specialist

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