

RELEASE DATE: June 15, 2007

APPLICATION RECEIPT DATE: August 1, 2007; 5:00 P.M.

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

PURPOSE OF THE RFA

On September 4, 2003, the National Institute of Allergy and Infectious Diseases (NIAID) established eight Regional Centers of Excellence (“RCE”s), identified by the United States Department of Health and Human Services as an essential component of the government’s strategic plan for biodefense research (<http://www.rcebiodefense.org/>). NIAID extended two additional awards, such that now ten RCEs exist, one in each of the ten federally designated regions of the United States. The Region V Great Lakes Regional Center of Excellence for Biodefense and Emerging Infectious Disease Research (“GLRCE”) is one of the ten regional centers, led by the University of Chicago (<http://www.glrce.org/>).

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. 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
- Novel adjuvants and medical 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. (In all, ten Regions exist, each consisting of a group of contiguous states.) Region V includes six states in the upper Midwest: Illinois, Indiana, Michigan, Minnesota, Ohio and Wisconsin. Presently, twenty-seven institutions in Region V are formally associated with the GLRCE, including: the University of Chicago, Northwestern University, Argonne National Laboratory, Battelle Memorial Institute, Illinois Institute of Technology, Illinois Institute of Technology Research Institute, Illinois

State University, Loyola University of Chicago, Mayo Clinic, Medical College of Wisconsin, Michigan State University, National Wildlife Health Center, the Ohio State University, Purdue University, University of Cincinnati, University of Illinois at Chicago, University of Illinois at Urbana-Champaign, University of Indiana, University of Michigan, University of Minnesota at Duluth, University of Minnesota at Minneapolis, University of Notre Dame, University of Toledo, University of Wisconsin at Madison, University of Wisconsin at Milwaukee, Wayne State University, and Wright State University. Twelve of these institutions currently house research programs funded by GLRCE: University of Chicago, Northwestern University, Argonne National Laboratory, Mayo Clinic, Medical College of Wisconsin, the Ohio State University, Purdue University, University of Cincinnati, University of Illinois, University of Michigan, University of Minnesota, and the University of Wisconsin.

The Great Lakes Regional Center of Excellence for Biodefense and Emerging Infectious Disease Research encourages institutions within the federally-designated Region V to join the consortium. To become a member of the consortium, an institution must send a formal letter of support to the Principal Investigator of the GLRCE, Olaf Schneewind, MD, PhD. For further information on joining the GLRCE, including a template letter, please contact Catherine Will, GLRCE Grants and Contracts Specialist, at cwill@bsd.uchicago.edu or 773-834-9174. Institutions new to the consortium are required to subscribe to the GLRCE Intellectual Property Plan. For a copy of the GLRCE Intellectual Property Plan, please contact Debra Anderson, GLRCE Associate Director, at danders1@bsd.uchicago.edu.

RESEARCH CURRENTLY SUPPORTED BY THE GLRCE

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

- *Bacillus anthracis*
- Botulinum neurotoxin
- *Yersinia pestis*
- *Francisella tularensis*
- *Brucella melitensis*
- *Rickettsia rickettsii*
- Ebola virus
- Flaviviruses
- Alphaviruses
- Rift Valley fever virus
- Pox viruses
- *Toxoplasma gondii*

RESOURCES OF THE GLRCE

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

- Microbial Informatics Resource Core
- Immunology Core
- *Clostridium botulinum* and Neurotoxin Core
- Small Animal Research Core

- Emergency Response

These resources are available for use by GLRCE researchers to enable access to specialized facilities or services that can accelerate research and development progress. For more information on core services or using the cores, please visit http://www.glrce.org/cores_facilities.php or contact Debra Anderson at danders1@bsd.uchicago.edu.

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

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

For information on using these resources, please contact Debra Anderson (danders1@bsd.uchicago.edu).

BSL3 LABORATORY SPACE

The GLRCE is directly associated with the NIAID Howard T. Ricketts Regional Biocontainment Laboratory (“RBL”), currently under construction at Argonne National laboratory in Argonne, Illinois (about 20 miles southwest of Chicago). This 48,000 square-foot Biosafety Level 3 facility, scheduled to open in the spring of 2008, will grant preference to GLRCE scientists and clinicians pursuing biodefense and emerging infectious disease research. The Ricketts RBL will also provide laboratory support for regional and/or national public health officials in the event of a biodefense or naturally-occurring epidemiological emergency. In the event of an emergency, the GLRCE will support governmental health officials by offering experts in topics related to biodefense and emerging infectious diseases. For more information on the Ricketts Laboratory, please visit <http://www.htrl.uchicago.edu/>.

RESEARCH PROGRAMS IN THE GLRCE

The GLRCE supports two programs that aim to increase the number of scientists performing basic biodefense research: the Developmental Projects Program and the Career Development Projects Program. The GLRCE Career Development Program is for new faculty and post-doctoral research associates and is specifically designed to recruit investigators without substantive experience in biodefense research in the field. Please visit <http://www.glrce.org> for Career Development funding opportunities for 2008. The GLRCE Developmental Projects program is open to all faculty level investigators, established and new, in biodefense research.

GLRCE DEVELOPMENTAL PROJECTS PROGRAM

The GLRCE employs the Developmental Projects Program to promote cutting-edge research that is likely to yield discoveries that translate into the creation of new vaccines, therapeutics and/or diagnostics to combat the NIAID Category A, B & C Priority Pathogens (<http://www.niaid.nih.gov/dmid/eid/erd.htm>). The hallmark of the Developmental Projects Program is its charge to fund “high risk/high reward” projects. Only small amounts of preliminary data are necessary to generate a DP proposal. In addition, the program intends to foster collaborations among consortium investigators, specifically between basic and clinical research laboratories, between microbiology laboratories and investigators in other basic disciplines (i.e. immunology, cell biology, chemistry), or between academic and industrial partners. Furthermore,

Developmental Project PIs should integrate the GLRCE Cores and National RCE Resources as much as possible into their research plans.

Five new “DP” awards are expected to result from this solicitation, with funding to begin on or about September 1, 2007. 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 one year, with a maximum project budget of \$100,000 direct costs.

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 date of proposal review (see below), all GLRCE investigators awarded must reside in institutions that formally belong to the GLRCE. To become a member of the consortium, an institution must send a formal letter of support to the Principal Investigator of the GLRCE, Olaf Schneewind, MD, PhD. For further information on joining the GLRCE, including a template letter, please contact Catherine Will, GLRCE Grants and Contracts Specialist, at cwill@bsd.uchicago.edu or 773-834-9174.

SUBMITTING AN APPLICATION

The initial application (due August 1, 2007 at 5:00p.m.) 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. Projects that include research involving human subjects must also include a NIAID Human Subject Research Concept Sheet. To obtain a copy of the Concept Sheet, please contact Debra Anderson, danders1@bsd.uchicago.edu;
- 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 August 1, 2007. 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 will conduct a review session of the applications in August 2007 to determine which applications will be recommended to the NIAID for funding through the consortium. Funding is anticipated to begin on or about September 1, 2007.

REVIEW CRITERIA

Applications will be reviewed for technical and programmatic merit by the GLRCE Executive Board (EB). The EB is comprised of established infectious disease researchers from the GLRCE member institutions, and has the primary responsibility for the review of all science in the consortium. Applications selected by the EB for funding must also be approved by the NIAID Program Officers prior to an award. The entire review and decision process is expected to take 4-8 weeks.

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 RCE programs* - Project use or enhancement of existing GLRCE resources; the establishment of a needed consortium resource;
- *Complementarity to the RCE biodefense mission* - Does project advance the long range plans of the GLRCE? Does project contribute to product development?; does the project apply a unique approach to the mission of the National Biodefense Network (<http://www.rcebiodefense.org/>)?;
- *Past performance* of the Principal Investigator;
- *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 five Developmental Project applications to the NIAID for funding, to begin on or about September 1, 2007. Awards are granted for a maximum of \$100,000 in direct costs. Funding for the Development Projects Program is contingent on continued funding of the GLRCE by the NIAID. Consortium Developmental Projects are evaluated on a routine basis, and their continued funding is dependent on satisfactory progress as judged by the Executive Board. The Executive Board then makes official GLRCE recommendations to the NIAID, whose program officers ultimately approve continued funding.

Subject to continued funding by NIAID, as well as the quantity and quality of applications and renewals during each review, additional GLRCE Developmental Project awards will be available on at least an annual basis.

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. In addition, if the proposal involves human subjects, a NIAID Concept form must be submitted with the application. To obtain a template Concept form, please contact Debra Anderson at danders1@bsd.uchicago.edu. For more information on PHS 398 forms, see http://grants1.nih.gov/grants/funding/phs398/section_1.html.

All proposed projects will be subject to the GLRCE Intellectual Property Plan. For a copy of the Intellectual Property Plan, please contact Debra Anderson at danders1@bsd.uchicago.edu.

GLRCE DEVELOPMENTAL PROJECT PROGRESS REPORTS

The progress of all Developmental Projects will be closely monitored by the GLRCE Executive Board and the NIAID. Quarterly scientific and financial progress reports must be submitted to the Executive Board via Debra Anderson, Associate Director of the GLRCE, on December 1, 2007 (for annual Center non-competitive renewal) as well as March 1, June 1 and September 1 of 2008. In addition, all GLRCE funded research must present progress at the annual GLRCE meeting, held each year in late fall.

WHERE TO SEND INQUIRIES

Direct questions about scientific/research issues to:

Debra Anderson, PhD
Associate Director
NIH/NIAID Region V Great Lakes Regional Center of Excellence
for Biodefense and Emerging Infectious Diseases
University of Chicago
920 E. 58th St., Suite 1117
Chicago, IL 60637
773-834-0566
danders1@bsd.uchicago.edu

Direct questions about financial or grants management matters, and application submission to:

Catherine Will
Grants and Contracts Specialist
NIH/NIAID Region V Great Lakes Regional Center of Excellence
for Biodefense and Emerging Infectious Diseases
University of Chicago
920 E. 58th St., Suite 1117
Chicago, IL 60637
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