

RELEASE DATE: September 12, 2007  
APPLICATION RECEIPT DATE: October 22, 2007

**NIH/NIAID Region V Great Lakes**  
**Regional Center of Excellence for Biodefense and Emerging Infectious Disease Research**  
*Request for Applications: New Opportunities 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.rcebiodefense.org/glrcel/>).

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 once again has the opportunity to apply for additional money for projects within the Center. These “New Opportunities” funds are not part of the Center’s original operational budget, but are intended for use by NIAID to fund new components and activities of the RCEs. These funds will be applied to objectives such as: enhancing the capabilities of the Centers and the Biodefense Network, encouraging inter-Center activities, and providing additional research, product development, and training opportunities. Because one of the goals for the RCEs is to develop vaccines, therapeutics, and diagnostics that are targeted to the Category A-C agents, projects directly related to achieving this goal will be given high priority. Projects exhibiting real novelty and genuine innovation will also be given extra consideration.

Applications for New Opportunities funds may include any of the following specific areas.

Highest priority areas:

- Product development related activities (Trans-Center or individual) such as advanced proof of concept, preclinical studies, phase I testing, technology transfer assistance (but not patent related activities), etc.
- New Collaborative projects involving investigators at two or more Centers.
- Trans-Center collaborations on existing projects, e.g., establishing collaborations between related projects so work is more synergistic.
- Training, especially for biosafety/biosecurity, animal care and use, etc.

Lower priority areas:

- Shared, large equipment for use within a Center or a region. Any such requests must clearly justify widespread immediate need for the equipment.
- Workshops or conferences for the entire Biodefense Network.
- Immunization costs for laboratory workers.

- ❑ Trans-Center resources such as new scientific Cores, e.g., a GMP core, PK/PD/Tox testing, assay development.

Not allowed:

- ❑ Additional Developmental Project or Career Development funds.
- ❑ Alteration and renovation (A&R) funds for facilities necessary to conduct the Center-funded research, if A&R funds were not included in the original RCE award or given subsequently in the second year-New Opportunity money. No RCE can receive more than \$500,000 A&R funds total over the lifetime of the grant.
- ❑ Supplements to existing projects unless for specific product development activities.
- ❑ Funds for extension of Developmental Projects beyond their current time limits.
- ❑ Funds to bring current Developmental Projects up to Research Project level.
- ❑ Supplements to projects/activities that had significant carryover funds.

Other areas may also be acceptable. For information on whether the concept you wish to propose fits the purpose of the RFA, please contact Olaf Schneewind, GLRCE Director (oschnee@bsd.uchicago.edu).

Trans-RCE proposals involving collaborative efforts with researchers or core facilities at two or more centers are strongly encouraged in the New Opportunities Program. GLRCE investigators seeking funding for trans-Center activities should submit written support from the Principal Investigators of other RCEs with the application package. All applicants proposing trans-Center activities should contact GLRCE Director, Olaf Schneewind, prior to submitting an application.

#### 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 at Bloomington, 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. Thirteen of these institutions currently house research programs funded by GLRCE: University of Chicago, Northwestern University, Argonne National Laboratory, Mayo Clinic, Medical College of Wisconsin, Michigan State University, Purdue University, University of Cincinnati, University of Illinois, University of Indiana, University of Michigan, University of Minnesota, and the University of Wisconsin. For an investigator to be funded by the GLRCE, his/her institution must be a formal member of the consortium.

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](mailto: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 Olaf Schneewind, GLRCE Director ([oschnee@bsd.uchicago.edu](mailto:oschnee@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*
- *Franciscella 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 Plan Component

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.rcebiodfense.org/glrc/cores\\_facilities.php](http://www.rcebiodfense.org/glrc/cores_facilities.php) or contact Olaf Schneewind, GLRCE Director ([oschnee@bsd.uchicago.edu](mailto:oschnee@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://nsrb.med.harvard.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, to be completed 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/>.

## OTHER 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 provides funding and training opportunities for new faculty or post-doctoral research associates and is specifically designed to recruit investigators without substantive experience in biodefense research in the field. Please look for a GLRCE Career Development Program RFA in 2007 on our web site (<http://www.rcebiodefense.org/glrce/>).

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. 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. Please look for a GLRCE Development Project RFA on our web site (<http://www.rcebiodefense.org/glrce/>).

## 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 the award, 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](mailto:cwill@bsd.uchicago.edu) or 773.834.9174.

## SUBMITTING AN APPLICATION

The initial application (due October 22, 2007 at 5:00p.m.) should utilize the latest PHS 398 application forms. Your proposal must be institutionally endorsed.

Applications should be submitted on PHS 398 forms and must include the following:

- ❑ Face page.
- ❑ Budget pages (NON-MODULAR)
- ❑ Up to five pages of text including an abstract, specific aims, research/project plan, and justification of the project in relation to the Strategic Plan for the Center. 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 Catherine at [cwill@bsd.uchicago.edu](mailto:cwill@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). Trans-Center proposals must include letters of support from Principal Investigators of at least 3 RCEs.

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

#### RECEIPT AND REVIEW SCHEDULE

Hard copy applications must be received by 5:00 p.m. on October 22, 2007. For administrative purposes, please also e-mail the application as a **Microsoft Word** file to Catherine Will at [cwill@bsd.uchicago.edu](mailto:cwill@bsd.uchicago.edu). The GLRCE Executive Board will conduct a review session of the New Opportunities Proposals the first week of November. Applications will be scored and ranked by the EB and sent to NIAID as part of the GLRCE New Opportunities Application (due December 1, 2007). GLRCE specific proposals will also be reviewed by a panel consisting of NIAID Program staff as well as program consultants as necessary. Trans-Center proposals will be reviewed by NIAID Program staff, RCE PIs and program consultants (as necessary). Funding of all New Opportunities projects must be approved by NIAID Program and Grants Management staff prior to issuing a revised Notice of Grant Award. The entire review and decision process may take up to 16 weeks.

#### 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. 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; the establishment of a needed consortium resource; how does the project contribute to the strategic plan of the GLRCE?

- *Complementarity to the RCE biodefense mission* - Does project advance the long range plans of the RCEs? Does project contribute to product development?; Does the project apply a unique approach to the mission of the National Biodefense Network?
- *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

Each Center will be eligible to apply for up to \$1,250,000 in **total costs**. Individual Center projects can request up to \$300,000 direct costs per year, with a 1 year maximum term. This cap will **not** apply to Trans-Center projects involving multiple RCEs such as network core facilities, network-wide conferences/workshops, and other activities that benefit the entire NIAID Biodefense Network, but will include collaborative research projects between two or more Centers. Proposals which exceed the \$300,000 cap must first receive budget approval from the GLRCE Director prior to submitting the application. New Opportunities projects must be competitively renewed each year, and are dependent on available funds for the entire RCE network New Opportunities Program. Therefore, one year projects are strongly encouraged. Supplemental Year New Opportunities projects are expected to begin on or about March 1, 2008. GLRCE New Opportunities projects are evaluated on a routine basis, and their continued funding is dependent on satisfactory progress as judged by the Executive Board.

#### 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 Catherine at [cwill@bsd.uchicago.edu](mailto:cwill@bsd.uchicago.edu). For more information on PHS 398 forms, see [http://grants1.nih.gov/grants/funding/phs398/section\\_1.html](http://grants1.nih.gov/grants/funding/phs398/section_1.html).

All proposed projects will be subject to the GLRCE Intellectual Property Plan.

#### GLRCE NEW OPPORTUNITIES PROJECT PROGRESS REPORTS

The progress of all New Opportunities Projects will be closely monitored by the GLRCE Executive Board and the NIAID. Quarterly scientific and financial progress reports must be submitted to the GLRCE Administrative Core on March 1, June 1 and September 1 of each year of funding. New Opportunities Projects are also expected to submit on December 1 progress reports for the yearly RCE non-competing renewal, due January 1. 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:

Olaf Schneewind, MD, PhD  
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  
[oschnee@bsd.uchicago.edu](mailto:oschnee@bsd.uchicago.edu)

Direct questions about financial or grants management matters 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  
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773-834-9174  
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