

## **NATIONAL INSTITUTE OF NEUROLOGICAL DISORDERS AND STROKE (NINDS) 2012**

The mission of NINDS is to reduce the burden of neurological disease—a burden borne by every age group, by every segment of society, by people all over the world. To this end, the Institute supports and conducts research on the healthy and diseased brain, spinal cord, and peripheral nerves. Hundreds of disorders afflict the nervous system. Common disorders such as stroke, epilepsy, Parkinson's disease, and autism are well-known. Many other neurological disorders are rare and known only to the individuals and families affected, their doctors, and scientists.

The NINDS SBIR/STTR program funds small business concerns to conduct innovative neuroscience research or neuroscience research and development (R/R&D) that has both the potential for commercialization and public benefit. NINDS is committed to helping small business concerns commercialize their technologies through its grant funding, technical assistance program participation, and outreach at meetings. NINDS encourages all Phase II applicants to apply to the [NIH Commercialization Assistance Program \(CAP\)](#) to gain assistance in transferring their products to the marketplace. The CAP program is open to all Phase II grants that were active in the past five years. NINDS is increasingly tracking the progress of its funded small business concerns and the products they develop. Funding priority will be given to those small business concerns that show not only their ability to develop products but their growth as a small business concern towards independence from the SBIR/STTR program.

### **Limited Amount of Award**

For budgetary, administrative, or programmatic reasons, NINDS may decrease the length of an award and/or the budget recommended by a review committee, or not fund an application. Generally, NINDS does not fund Phase I applications greater than \$350,000 total cost per year for up to 2 years or Phase II applications greater than \$1,000,000 total cost per year for up to 3 years. Applicants considering a requested budget greater than these limits are strongly encouraged to contact program staff before submitting an application.

### **Phase IIB Competing Renewal Awards**

In addition to the traditional Phase I and II applications, NINDS accepts Phase IIB SBIR/STTR Competing Renewal applications through specific opportunities that focus on the commercialization of SBIR and STTR developed technologies. These opportunities can be found on the NIH SBIR webpage: [http://www.ninds.nih.gov/funding/small-business/small\\_business\\_funding\\_opportunities.htm](http://www.ninds.nih.gov/funding/small-business/small_business_funding_opportunities.htm).

## **RESEARCH TOPICS OF INTEREST TO NINDS**

### **General Areas of Interest**

The NINDS accepts a broad range of small business applications that are significant, innovative, and relevant to its mission. Examples of research topics within the mission of NINDS that may be of interest to small businesses are shown below. This list is not all inclusive and some research areas fall into multiple categories.

1. Therapeutics and Diagnostics Development for Neurological Disorders, including biomarker and diagnostic assays, therapeutics (drugs, biologics, and/or devices) for treatment of neurological disorders, and technologies/methodologies to deliver therapeutics to the central nervous system.
2. Clinical and Rehabilitation Tools, including intraoperative technologies for neurosurgeons, rehabilitation devices and programs for neurological disorders, and brain monitoring systems

3. Technology and Tools, including imaging technologies to image the nervous system, neural interfaces technologies, and tools for neuroscience research and drug development.

In addition to the research topics listed, NINDS also encourages applications in specific program areas. For additional information about NINDS program announcements, please visit our small business home page at: <http://www.ninds.nih.gov/funding/small-business/>.

### **Clinical Trials**

The NINDS is committed to identifying effective treatments for neurological disorders by supporting well-executed clinical trials. NINDS accepts SBIR and STTR clinical trial applications through specific opportunities, which can be found on the NIH SBIR webpage: [http://www.ninds.nih.gov/funding/small-business/small\\_business\\_funding\\_opportunities.htm](http://www.ninds.nih.gov/funding/small-business/small_business_funding_opportunities.htm). Other human subjects research can be submitted through the Omnibus solicitation, NINDS may decline funding of any application that includes human subjects for programmatic or administrative reasons. SBIR applicants considering projects involving human subjects research are strongly encouraged to contact Stephanie Fertig or Joanne Odenkirchen (contact information provided below) within the NINDS Office of Clinical Research.

Joanne Odenkirchen, M.P.H.  
Clinical Research Project Manager, Office of Clinical Research  
301-496-3104  
Email: [jo21x@nih.gov](mailto:jo21x@nih.gov)

### **NINDS Cooperative Program in Translational Research**

Although translational research is supported through the general SBIR/STTR program announcement, the NINDS also has a Cooperative Program in Translational research ([PAR-11-296](#)). The NINDS Cooperative Program encourages Phase II and Fast-Track applications that directly address the identification and pre-clinical testing of new therapeutics for neurological disorders. The program will facilitate solicitation, development, and review of therapy-directed projects to accelerate the translation of basic research discoveries into therapeutic candidates for clinical testing. This program is specifically directed at projects that include therapeutic leads with demonstrated activity against the intended disease target. The program supports pre-clinical optimization and testing of these leads and projects must be sufficiently advanced that an IND or IDE application to the FDA can be submitted by the end of the project period. The program does not support early-stage therapeutic discovery activities such as high throughput screening. The program also excludes clinical research, basic research, and studies of disease mechanism. This is a milestone-driven cooperative agreement program involving participation of NINDS staff in the development of the project plan and monitoring of research progress. For more information on the NINDS Cooperative Program in Translational Research-Small Business Awards (SBIR[U44]): <http://grants.nih.gov/grants/guide/pa-files/PAR-11-296.html>.

Due to the unique requirements of the NINDS Cooperative Program in Translational Research, applicants are strongly encouraged to consult with Dr. Linda McGavern at least three months prior to the next receipt date.

Dr. Linda McGavern, Ph.D.  
Program Manager, Office of Translational Research  
301-496-1779  
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### **Countermeasures Against Chemical Threats**

NINDS manages the NIH Countermeasures Against Chemical Threats (CounterACT) program. CounterACT supports research and development on new and improved therapeutics or diagnostic technologies to prevent or mitigate the toxic effects from exposure to chemical threats, defined as toxic

chemical agents that could be used in a terrorist attack against civilians, or those that could be released at toxic levels by accident or natural disaster. This includes the development of new (or support of existing) partnerships between small business and not-for-profit laboratories engaged in this research. The scope of research supported includes early screening for compounds with the desired biological activity, advanced preclinical and efficacy testing, through clinical research with promising candidate therapeutics. For more information on this program, including specific program announcements, please see: [www.ninds.nih.gov/counteract](http://www.ninds.nih.gov/counteract). Applicants are strongly encouraged to consult with Dr. David Jett to determine the programmatic relevance of their proposed research.

David A. Jett, Ph.D.  
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301-496-6035  
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**For additional information on research topics, contact:**

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**For administrative and business management questions, contact:**

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