
GRANTS AND CONTRACTS

INSTITUTIONAL CLINICAL AND TRANSLATIONAL SCIENCE AWARD (U54): RFA-RM-07-002

National Institutes of Health (NIH)

This request for applications (RFA) is developed as a Roadmap initiative. All NIH Institutes and Centers participate in Roadmap initiatives. This RFA will be administered by the National Center for Research Resources on behalf of the NIH.

Letter of intent receipt date: December 18, 2006

Application receipt date: January 17, 2007

Growing barriers between clinical and basic research, along with the ever-increasing complexities involved in conducting clinical research, are making it more difficult to translate new knowledge to the clinic and back again to the bench. These challenges are limiting professional interest in the field and hampering the clinical research enterprise at a time when it should be expanding. The purpose of this initiative is to assist institutions to create a uniquely transformative, novel, and integrative academic home for clinical and translational science that has the resources to train and advance a cadre of well-trained multi- and interdisciplinary investigators and research teams with access to innovative research tools and information technologies to promote the application of new knowledge and techniques to patient care. Clinical and translational science awards (CTSAs) will attract basic, translational, and clinical investigators; community clinicians; clinical practices; networks; professional societies; and industry to develop new professional interactions, programs, and research projects. Through innovative advanced degree programs, CTSAs will foster a new discipline of clinical and translational science that will be much broader and deeper than their separate components (definitions of clinical and translational science are provided in Section I.1 of this document). To succeed, CTSAs will need institutional support and the status of a major administrative entity within the applicant institution and a principal investigator (PI) who has authority, perhaps shared with other high-level institutional officials, over requisite space, resources, faculty appointments, protected time, and promotion. NIH anticipates that diverse models will be proposed to fulfill these goals and welcomes innovative proposals that meet the needs of both the local institution and the wider research

community. This RFA invites applications for institutional CTSAs that will enable applicants to innovate and transform their own environment to develop and advance clinical and translational science as a distinct discipline. NIH Roadmap resources will give institutions the flexibility to develop their existing resources and talent and to propose ways to increase the efficiency and speed of clinical and translational research. The academic home, which can be a center, department, or institute (C/D/I), is expected to include faculty who conduct original research, develop graduate and postgraduate training curricula, and lead programs that integrate clinical and translational science across multiple departments, schools, research institutes, and hospitals. Applicants will be expected to define the key functions, components, governance, and structure of their C/D/I. They should describe the existing and planned activities that would be integrated to create the CTSA and the role that the participating schools and departments within the applicant organization, affiliated institutions, community, foundations, and industry would play. The C/D/I will provide career paths in clinical and translational science through research education, training, and career development leading to advanced degrees (MS or PhD). The C/D/I will work in close cooperation with the activities of the NIH Roadmap, NIH Institutes and Centers, and other appropriate trans-NIH activities. The C/D/I at each institution will be expected to complement and interact with existing centers that are funded by the categorical institutes of the NIH and to interact with affiliated institutions and industry. The total funds available for the new awards are approximately \$38 million. Awards will vary in size owing to the consolidation of multiple programs within the CTSA program. Applicants may request total costs up to \$6 million annually for 5 years in addition to the combined current total costs of certain NIH awards (National Center for Research Resources [NCRR] K12, K30, M01, and Roadmap T32 and K12) held by the applicant institution and its affiliates, as stated as "Approved Budget" in the last Notice of Grant Award issued prior to October 1, 2006. Revised applications should use the NIH award budget base of the previous unsuccessful application. If the application is successful, all of the above-listed awards at each participating institution will be reconfigured into the CTSA program. It is possible for more than one of each type

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of award to be included in the CTSA and for more than one institution to participate in a single CTSA; however, a single institution can participate in only one CTSA. Institutions without the above awards may request up to \$6 million annually in total costs. Non-NICRR and Roadmap NIH categorical awards will not be included in the reconfiguration, but it is anticipated that they will continue to benefit from the CTSA infrastructures. Up to eight awards are anticipated from this solicitation. The NIH intends to issue solicitations for additional CSAs in future years. Applicants must submit a single comprehensive U54 Cooperative Agreement application that includes a research education, training, and career development section. This section must address specific application requirements for a clinical and translational research education component and a clinical and translational science institutional career development scholars component. NIH cooperative agreements are subject to oversight by NIH staff, and the CSAs will serve as regional or national resources for special research purposes, with NIH staff helping identify appropriate priority needs. To aid in oversight, these awards will be milestone driven, with subsequent funding based on the achievement of specific, well-defined milestones. Eligible organizations include domestic institutions, universities, academic health centers, or other research organizations conducting clinical and translational research; however, a graduate school accredited to award higher degrees (eg, master's degree or PhD) in clinical research must be included. Examples of acceptable higher degrees include MS and PhD in topics such as clinical research, public health, pharmacology, nursing, or epidemiology. Partnerships among schools of medicine, dentistry, nursing, pharmacy, osteopathy, public health, engineering, and other clinically related institutions are strongly encouraged, as is the inclusion of other relevant clinical research entities and organizations. Foreign institutions are not eligible to apply. Eligible PIs are expected to have the institutional authority to direct the C/D/I or other entity that comprises the proposed institutional home for clinical and translational science. The PI and directors of key functions should have direct knowledge and hands-on involvement in the daily activities of the C/D/I, and NIH would look favorably on their participation as full-time faculty members of the proposed C/D/I. It is expected that the PI would be an established clinician scientist who reports directly to an official with broad transinstitutional authority. Individuals from underrepresented racial and ethnic groups and individuals with disabilities are always encouraged to apply for NIH programs. An institution

can only submit, or be part of, a single application in response to this RFA, which should include detailed evidence of significant institutional commitment. A presubmission videoconference will be conducted on Thursday, October 5, 2006, between 2:00 and 4:00 pm, at which NICRR and other NIH staff will explain the goals and objectives of the CTSA program and answer questions. All prospective applicants are invited to view the meeting through videoconference or videocast (Webcast). Additional information on video-casting will be available at <<http://www.nicrr.nih.gov/clinicaldiscipline.asp>>, and the meeting videocast will be archived at <videocast.nih.gov>. A frequently asked questions (FAQ) Web site is available at <<http://www.nicrr.nih.gov/clinicaldiscipline.asp>>. A listserv (CTSA-L; <http://list.nih.gov/cgi-bin/show_list_archives>) will be used to notify applicants of the Webcast and any changes to the FAQ list.

Complete details are available at <<http://grants1.nih.gov/grants/guide/rfa-files/RFA-RM-07-002.html>>.

TECHNOLOGY DEVELOPMENT OF IMAGE-GUIDED INTERVENTIONS: PHASE I (R21): RFA-EB-06-003

National Institutes of Health (NIH)

National Institute of Biomedical Imaging and Bioengineering (NIBIB)

National Cancer Institute (NCI)

Letter of intent receipt date: September 25, 2006

Note: On-time submission requires that applications be successfully submitted to Grants.gov no later than 5:00 pm local time (of the applicant institution/organization).

Application submission/receipt date: October 23, 2006

This funding opportunity announcement (FOA) solicits exploratory/developmental (R21) grant applications from applicant organizations that propose to develop high-impact, disruptive technologies for image-guided interventions (IGIs). As defined here, IGIs integrate treatment with imaging technologies at the point of patient care. The long-term goal of the IGI initiative is to produce disruptive technologies that will replace current treatments with minimally invasive IGIs. A disruptive technology is a new technological innovation that displaces the existing dominant technology. Examples of disruptive technologies include minimally invasive, image-guided procedures that replace invasive surgery or low-cost IGIs. This FOA is intended to support the first phase of a two-phase project that will deliver high-clinical impact IGIs. Multidisciplinary collaborations and partnerships with industry are encouraged. In addition, development of multipotential technologies that might have applicability across a range

of clinical conditions is also encouraged. This FOA will use the exploratory/developmental R21 grant mechanism. A total of \$5,000,000 is committed to this FOA for payment of applications responsive to this announcement. Awards issued under this FOA are contingent on the availability of funds and the submission of a sufficient number of meritorious applications. The anticipated number of awards is 10 to 15. Owing to the fact that the nature and scope of the proposed research will vary from application to application, it is anticipated that the size and duration of each award will also vary. The total amount awarded and the number of awards will depend on the mechanism numbers, quality, duration, and costs of the applications received. An applicant may request a project period of up to 3 years and a budget for total direct costs of up to \$300,000 per year. It is anticipated that most applications will request \$100,000 to \$300,000 per year. Eligible organizations include for-profit and nonprofit organizations; public or private institutions, such as universities, colleges, hospitals, and laboratories; units of state and local government; eligible institutions of the federal government; domestic and foreign institutions; faith- and community-based organizations; Indian/Native American tribal governments (federally recognized); Indian/Native American tribal governments (other than federally recognized); and Indian/Native American tribally designated organizations. Individuals with the skills, knowledge, and resources necessary to carry out the proposed research are invited to work with their institution to develop an application for support. Individuals from underrepresented racial and ethnic groups and individuals with disabilities are always encouraged to apply for NIH support. Applicants may submit more than one application provided that each application is scientifically distinct. The SF424 (R&R) application guide for this FOA is located at these Web sites:

http://grants1.nih.gov/grants/funding/424/SF424_RR_Guide_General_Ver2.doc (MS Word)

http://grants1.nih.gov/grants/funding/424/SF424_RR_Guide_General_Ver2.pdf (PDF)

Complete details are available at <http://grants.nih.gov/grants/guide/rfa-files/RFA-EB-06-003.html>.

BIOENGINEERING APPROACHES TO ENERGY BALANCE AND OBESITY (R21): RFA-HL-07-007

National Institutes of Health (NIH)

National Science Foundation (NSF)

National Heart, Lung, and Blood Institute (NHLBI)

National Institute on Aging (NIA)

National Institute of Biomedical Imaging and Bioengineering (NIBIB)

National Cancer Institute (NCI)

National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)

Letter of intent receipt date: November 24, 2006

Note: On-time submission requires that applications be successfully submitted to Grants.gov no later than 5:00 pm local time (of the applicant institution/organization).

Application submission/receipt date: December 22, 2006

The purpose of this funding opportunity announcement (FOA) is to solicit applications to develop and validate new and innovative engineering approaches to address clinical problems related to energy balance, intake, and expenditure. Novel sensors, devices, imaging, and other technologies, including technologies to detect biochemical markers of energy balance, are expected to be developed and evaluated by collaborating engineers, physical scientists, mathematicians, and scientists from other relevant disciplines with expertise in obesity and nutrition. Basic and applied scientific applications with rigorous hypothesis-testing designs or for design-directed research are encouraged. The goal is to increase the number of useful technologies and tools available to scientists to facilitate their research in energy balance and health. Eventually, these research tools should facilitate therapeutic advances and behavioral changes to address such problems as weight control and obesity. This FOA will use the R21 grant mechanism (see <http://grants1.nih.gov/grants/funding/r21.htm>). The participating organizations intend to commit a total of \$3,050,000 in fiscal year 2007 to this FOA for payment of applications responsive to this announcement. The anticipated number of awards is 10 to 15. Awards issued under this FOA are contingent on the availability of funds and the submission of a sufficient number of meritorious applications. Owing to the fact that the nature and scope of the proposed research will vary from application to application, it is anticipated that the size and duration of each award will also vary. The total amount awarded and the number of awards will depend on the mechanism numbers, quality, duration, and costs of the applications received. The total project period for an application submitted in response to this funding opportunity may not exceed 3 years. Direct costs are limited to \$450,000 over a 3-year period, with no more than \$150,000 in direct costs allowed in any single year. Eligible organizations include for-profit and nonprofit organizations; public and private institutions, such as universities, colleges, hospitals, and laboratories; units of state and local governments; eligible agencies of the federal govern-

ment; domestic and foreign institutions/organizations; faith- and community-based organizations; Indian/Native American tribal governments (federally recognized); Indian/Native American tribal governments (other than federally recognized); and Indian/Native American tribally designated organizations. Individuals with the skills, knowledge, and resources necessary to carry out the proposed research are invited to work with their institution to develop an application for support. Individuals from underrepresented racial and ethnic groups and individuals with disabilities are always encouraged to apply for NIH support. Applicants may submit more than one application provided that each application is scientifically distinct. The SF424 (R&R) application guide for this FOA is located at these Web sites:

http://grants1.nih.gov/grants/funding/424/SF424_RR_Guide_General_Ver2.doc (MS Word)

http://grants1.nih.gov/grants/funding/424/SF424_RR_Guide_General_Ver2.pdf (PDF)

Complete details are available at <http://grants1.nih.gov/grants/guide/rfa-files/RFA-HL-07-007.html>.

NATIONAL RESEARCH SERVICE AWARD POSTDOCTORAL FELLOWSHIPS IN EPIDEMIOLOGY, CLINICAL TRIALS, AND OUTCOMES RESEARCH IN ORTHOPEDIC SURGERY (F32): PAR-06-539

National Institutes of Health (NIH)

Orthopaedic Research and Education Foundation (OREF)

National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)

Application receipt dates: October 23, 2006; February 23, June 23, October 23, 2007; and February 23, June 23, 2008

NIAMS, along with OREF, announces the availability of individual National Research Service Award (NRSA) postdoctoral fellowships to support the training of physicians with expertise in orthopedic surgery to supplement that knowledge with training in epidemiology, clinical trials, and outcomes research. These fellowships are intended to support up to 2 years of advanced training in the relevant methodologies, which is to be used to obtain a master of public health degree (or similar relevant area of study, such as biostatistics) and/or a PhD in epidemiology to qualify the fellow to pursue a career in these areas as they relate to orthopedic surgery. This program announcement (PAR) will use the NIH Individual Postdoctoral NRSA Fellowship Award (F32) mechanism. The total project period for an application submitted in response to this PAR may not exceed a 2 years. The requested project period should be reduced by the amount of

time a fellow has received support on any previous NRSA postdoctoral fellowship, including institutional NRSA training grants (T32s), so that the total NRSA support does not exceed 3 years. For further information, refer to the “NIH Guidelines for the NIH National Research Service Awards for Individual Postdoctoral Fellows” (F32), published in the NIH *Guide for Grants and Contracts* (PA-06-373) (<http://grants.nih.gov/grants/guide/pa-files/PA-06-373.html>). The NIAMS intends to fund up to four new applications responding to this PAR in fiscal year 2007 and/or 2008 and/or 2009 subject to the availability of resources and receipt of sufficiently meritorious applications. The estimated funds (total costs) available for the first year of support of this program are \$150,000. Eligible organizations include for-profit and nonprofit organizations; public and private institutions, such as universities, colleges, hospitals, and laboratories, units of state and local governments; eligible agencies and laboratories of the federal government, including NIH intramural laboratories; and domestic and foreign institutions/organizations. Individuals with the skills, knowledge, and resources necessary to carry out the fellowship research training are invited to work with their institutions to develop an application for support. Individuals from underrepresented racial and ethnic groups and individuals with disabilities are always encouraged to apply for NIH support. The applicant fellow must have an MD, a DO, or an equivalent degree and have completed at least 2 years of clinical orthopedic surgery training in an accredited program prior to the commencement of the fellowship. Clinical orthopedic surgery training may not have been completed more than 5 years prior to submission of the application. The individual must also meet the criteria for the NRSA individual postdoctoral fellows (F32) described in PA-00-104, available in the NIH *Guide for Grants and Contracts* (release date December 11, 1998; available at <http://grants.nih.gov/grants/guide/pa-files/PA-00-104.html>). Applicant fellows must be citizens or noncitizen nationals of the United States or have been lawfully admitted to the United States for permanent residence and have in their possession an alien registration receipt card (I-151 or I-551) or other legal verification of such status at the time of award. Noncitizen nationals are generally persons born in outlying possessions of the United States (ie, American Samoa and Swains Island). Individuals on temporary or student visas are not eligible. Individuals may apply for the F32 in advance of admission to the United States as a permanent resident, recognizing that no award will be made until legal verification of permanent resident

status is provided. Before submitting a fellowship application, the applicant must identify a sponsoring institution and an individual who will serve as a sponsor (also called mentor or supervisor) and will supervise the training and research experience. The sponsoring institution may be private (profit or nonprofit) or public, including the NIH intramural programs and other federal laboratories. The applicant's sponsor should be an active investigator in either orthopedic surgery research or epidemiology, clinical trials, or outcomes research. In some instances, it may be advisable for a secondary sponsor to complement the primary sponsor's expertise. The sponsor must document the availability of staff research support, didactic training, and facilities for high-quality research training. An individual may not have two or more competing NIH fellowship applications pending review concurrently. In addition, the NIH Center for Scientific Review will not accept for review any application that is essentially the same as one already reviewed. This does not preclude the submission of a substantial revision of an application already reviewed, but such applications must include an introduction addressing the previous critique. Applicants submitting revised applications must follow the instructions for revised applications, PHS 416-1 (revised October 2005). Up to two revised applications may be submitted. Application materials and instructions are available at <http://grants.nih.gov/grants/funding/416/phs416.htm>. It is important to note that the PHS 416-1 application form has been restructured and the instructions have been significantly (modified October 2005). See <http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-06-016.html>, released December 9, 2005.

Complete details are available at <http://grants.nih.gov/grants/guide/pa-files/PAR-06-539.html>.

CANCER EDUCATION GRANTS PROGRAM (R25): PAR-06-540

National Institutes of Health (NIH)

National Cancer Institute (NCI)

Note: On-time submission requires that applications be successfully submitted to Grants.gov no later than 5:00 pm local time (of the applicant institution/organization).

Letter of intent receipt date(s): Not applicable.

Application receipt date(s): Standard dates apply; see <http://grants.nih.gov/grants/funding/submissionschedule.htm>.

This funding opportunity announcement (FOA) uses the NIH research education (R25) grant

mechanism to support the following types of programs: innovative educational programs intended to motivate biomedical and other health science students to pursue cancer-related careers; short courses to update cancer research scientists in new scientific methods, technologies, and findings; training of cancer care clinicians and community health care providers in evidence-based cancer prevention and control approaches; and development of effective innovative education (dissemination) approaches to translate knowledge gained from science (discovery) into public health and community applications (delivery). Owing to the fact that the nature and scope of the proposed research education program will vary from application to application, it is anticipated that the size and duration of each award will also vary. The total amount awarded and the number of awards will depend on the quality, duration, and costs of the applications received. The total project period for an application submitted in response to this funding opportunity may not exceed 5 years. Direct costs are limited to \$300,000 per year. Eligible organizations include public and state-controlled institutions of higher education; private institutions of higher education; nonprofit organizations with 501(c)(3) IRS status (other than an institution of higher education); nonprofit organizations without 501(c)(3) IRS status (other than an institution of higher education); small business; for-profit organization (other than small business); state government; Indian/Native American tribally designated organizations; and community- and faith-based organizations. Individuals with the skills, knowledge, and resources necessary to carry out the proposed research education program are invited to work with their institution to develop an application for support. Individuals from underrepresented racial and ethnic groups and individuals with disabilities are always encouraged to apply for NIH support. Applicants may submit more than one application provided that each application is scientifically distinct. Research education programs may not be transferred from one institution to another unless strongly justified (see Section VI.2). The NCI Division of Extramural Activities will convene initial merit review.

The SF424 (R&R) application guide for this FOA is located at these Web sites:

http://grants1.nih.gov/grants/funding/424/SF424_RR_Guide_General_Ver2.doc (MS Word)

http://grants1.nih.gov/grants/funding/424/SF424_RR_Guide_General_Ver2.pdf (PDF)

Complete details are available at <http://grants.nih.gov/grants/guide/pa-files/PAR-06-540.html>.

FUNCTIONAL LINKS BETWEEN THE IMMUNE SYSTEM, BRAIN FUNCTION, AND BEHAVIOR (R21): PA-06-533

National Institutes of Health (NIH)

National Institute of Mental Health (NIMH)

National Institute on Aging (NIA)

National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)

National Institute of Biomedical Imaging and Bioengineering (NIBIB)

National Institute on Drug Abuse (NIDA)

National Institute of Neurological Disorders and Stroke (NINDS)

National Cancer Institute (NCI)

Note: On-time PA-06-533 submission requires that applications be successfully submitted to Grants.gov no later than 5:00 pm local time (of the applicant institution/organization).

Application submission/receipt date(s): Standard dates apply; see: <<http://grants1.nih.gov/grants/funding/submissionschedule.htm>>.

NIMH, NIA, NIAMS, NIDA, NIBIB, NINDS, and NCI request research grant applications to study neuroimmune molecules and mechanisms involved in regulating normal and pathologic central nervous system function. This funding opportunity announcement (FOA) will use the exploratory/development (R21) grant mechanism and runs in parallel with an FOA of identical scientific scope, PA-05-054, which solicits applications under the NIH research project (R01). Awards issued under this FOA are contingent on the availability of funds and the submission of a sufficient number of meritorious applications. Owing to the fact that the nature and scope of the proposed research will vary from application to application, it is anticipated that the size and duration of each award

will also vary. The total amount awarded and the number of awards will depend on the mechanism numbers, quality, duration, and costs of the applications received. The total project period for an application submitted in response to this funding opportunity may not exceed 2 years. Direct costs are limited to \$275,000 over an R21 2-year period, with no more than \$200,000 in direct costs allowed in any single year. Eligible organizations include for-profit and nonprofit organizations; public and private institutions, such as universities, colleges, hospitals, and laboratories; units of state and local governments; eligible agencies of the federal government; domestic and foreign institutions/organizations; faith- and community-based organizations; Indian/Native American tribal governments (federally recognized); Indian/Native American tribal governments (other than federally recognized); and Indian/Native American tribally designated organizations. Individuals with the skills, knowledge, and resources necessary to carry out the proposed research are invited to work with their institution to develop an application for support. Individuals from underrepresented racial and ethnic groups and individuals with disabilities are always encouraged to apply for NIH support. Applicants may submit more than one application provided that each application is scientifically distinct.

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http://grants1.nih.gov/grants/funding/424/SF424_RR_Guide_General.pdf (PDF)

Complete details are available at <<http://grants.nih.gov/grants/guide/pa-files/PA-06-533.html>>.

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I certify that the statements made by me above are correct and complete.

Brian Decker, Publisher