

■ A CENTRALIZED PROTEIN SEQUENCE AND FUNCTION RESOURCE (U41): RFA-HG-10-004

Components of Participating Organizations

*National Human Genome Research Institute
National Institute of General Medical Sciences*

Application Receipt Date(s): May 12, 2010

This FOA is issued jointly by The National Human Genome Research Institute (NHGRI) and The National Institute of General Medical Sciences (NIGMS) and solicits grant applications from institutions/organizations to support a centralized protein sequence and function resource (hereafter called "Resource") that will serve as a repository of curated protein sequences and will provide high quality annotation of the functional information.

This FOA will utilize the U41 grant mechanism. The participating NIH institutes intend to commit approximately \$6.0 million in FY2010 to fund a single grant in response to this FOA. The total project period for an application submitted in response to this funding opportunity may not exceed three years. Direct costs may be requested up to \$5.5 million per year and up to \$6.0 million in total costs.

Eligible institutions and organizations include: public or state controlled institutions of higher education; private institutions of higher education; Hispanic-serving institutions; Historically Black Colleges and Universities; Tribally Controlled Colleges and Universities; Alaska native- and native Hawaiian-serving institutions; nonprofit organizations with 501(c)(3) IRS status (other than institutions of higher education); nonprofit organizations without 501(c)(3) IRS status (other than institutions of higher education); for-profit organizations (other than small businesses); state governments; Indian/Native American tribal governments (federally recognized) Indian/Native American tribally designated organizations; county governments; city or township governments; special district governments; non-domestic (non-U.S.) entities (foreign organizations); and eligible agencies of the Federal Government. Individuals with the skills, knowledge, and resources necessary to carry out the proposed research are invited to work with their institution/organization to develop an application for support. Individuals from under-represented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for NIH support. More than one PD/PI (i.e., multiple PDs/Pis), may be designated on the application. Applicants may submit one application. Resubmission applications are not permitted in response to this FOA. Resubmission applications are not permitted in response to this FOA. This FOA uses non-standard due dates.

Complete details available at <http://grants.nih.gov/grants/guide/rfa-files/RFA-HG-10-004.html>.

■ SHIFT AWARD: SMALL BUSINESSES HELPING INVESTIGATORS TO FUEL THE TRANSLATION OF SCIENTIFIC DISCOVERIES [SBIR: R43/R44]: PA-10-122

Components of Participating Organizations

*National Institutes of Health
National Center for Complementary and Alternative Medicine
National Center for Research Resources
National Heart, Lung, and Blood Institute
National Institute on Aging
National Institute on Alcohol Abuse and Alcoholism
National Institute of Allergy and Infectious Diseases*

National Institute of Arthritis and Musculoskeletal and Skin Diseases

Eunice Kennedy Shriver National Institute of Child Health and Human Development

National Institute on Drug Abuse

National Institute of Diabetes and Digestive and Kidney Diseases

National Institute of General Medical Sciences

Application Due Date(s): Standard dates apply, see <http://grants1.nih.gov/grants/funding/submissionschedule.htm>

AIDS Application Due Date(s): Standard dates apply, see <http://grants1.nih.gov/grants/funding/submissionschedule.htm#AIDS>.

The primary objectives of the SHIFT SBIR initiative are: (1) to foster research that is translational in nature and (2) to transform academic scientific discoveries into commercial products and services. Academic researchers can be a driving force for new products and services in a small business concern (SBC). A major feature of the SHIFT program includes the requirement for an investigator who is primarily employed by a United States research institution at the time of application to transition to a small business concern (SBC) and be primarily employed (more than 50% time) by the SBC by or at the time of award. A SHIFT SBIR grant enables an SBC to increase both its scientific research staff and its core competencies. The Project Director/Principal Investigator (PD/PI) may also facilitate SBC licensing of intellectual property (IP) from the PD/PI's prior academic institutions, promote collaboration opportunities with academic investigators, and enable better access to academic resources.

This FOA will utilize the SBIR (R43/R44) grant mechanisms for Phase I, Phase II, and Fast-Track applications. Awards issued under this FOA are contingent upon the availability of funds and the submission of a sufficient number of meritorious applications. The total amount awarded and the number of awards will depend upon the quality, duration, and costs of the applications received. Well-justified budgets up to \$200,000 total costs per year and time periods up to 2 years may be requested for Phase I. Well-justified budgets up to \$750,000 total costs per year and time periods up to 3 years may be requested for Phase II. Phase II Competing Renewal applications must be submitted in accordance with participating Institute's or Center's specific budget limitations described in the current SBIR/STTR Program Descriptions and Research Topics of the NIH, CDC and FDA.

Only United States small business concerns (SBCs) are eligible to submit SBIR applications. A small business concern is one that, at the time of award of SBIR Phase I and Phase II, meets all of the following criteria:

1. Is organized for profit, with a place of business located in the United States, which operates primarily within the United States or which makes a significant contribution to the United States economy through payment of taxes or use of American products, materials or labor;
2. Is in the legal form of an individual proprietorship, partnership, limited liability company, corporation, joint venture, association, trust or cooperative, except that where the form is a joint venture, there can be no more than 49 percent participation by foreign business entities in the joint venture;
3. Is at least 51 percent owned and controlled by one or more individuals who are citizens of, or permanent resident aliens in, the United States, or it must be a for-profit business concern that is at least 51% owned and controlled by another

for-profit business concern that is at least 51% owned and controlled by one or more individuals who are citizens of, or permanent resident aliens in, the United States, except in the case of a joint venture, where each entity to the venture must be 51 percent owned and controlled by one or more individuals who are citizens of, or permanent resident aliens in, the United States; and;

4. Has, including its affiliates, not more than 500 employees.

SBCs must also meet the other regulatory requirements found in 13 C.F.R. Part 121. Business concerns, other than investment companies licensed, or state development companies qualifying under the Small Business Investment Act of 1958, 15 U.S.C. 661, et seq., are affiliates of one another when either directly or indirectly, (a) one concern controls or has the power to control the other; or (b) a third-party/parties controls or has the power to control both.

Control can be exercised through common ownership, common management, and contractual relationships. The term “affiliates” is defined in greater detail in 13 C.F.R. 121.3-2(a). The term “number of employees” is defined in 13 C.F.R. 121.3-2(t).

Business concerns include, but are not limited to, any individual (sole proprietorship), partnership, corporation, joint venture, association, or cooperative. Further information may be obtained by contacting the Small Business Administration Office of Size Standards (<http://sba.gov/size>).

One of the circumstances that would lead to a finding that an organization is controlling or has the power to control another organization involves sharing common office space and/or employees and/or other facilities (e.g., laboratory space). Access to special facilities or equipment in another organization is permitted (as in cases where the awardee organization has entered into a subcontractual agreement with another organization for a specific, limited portion of the research project). However, research space occupied by an SBIR awardee organization must be space that is available to and under the control of the SBIR awardee for the conduct of its portion of the proposed project.

Title 13 CFR 121.3 also states that control or the power to control exists when “key employees of one concern organize a new concern ... and serve as its officers, directors, principal stockholders, and/or key employees, and one concern is furnishing or will furnish the other concern with subcontracts, financial or technical assistance, and/or other facilities, whether for a fee or otherwise.” Where there is indication of sharing of common employees, a determination will be made on a case-by-case basis of whether such sharing constitutes control or the power to control.

For purposes of the SBIR program, personnel obtained through a Professional Employer Organization or other similar personnel leasing company may be considered employees of the awardee. This is consistent with SBA’s size regulations, 13 CFR 121.106 – Small Business Size Regulations.

Note: In determining size, SBA considers stock options, convertible securities, and agreements to merge (including agreements in principle) to have a present effect on the power to control a concern. SBA treats such options, convertible securities, and agreements as though the rights granted have been exercised. See http://edocket.access.gpo.gov/cfr_2005/janqtr/pdf/13cfr121.103.pdf.

All SBIR grant applications will be examined with the above eligibility considerations in mind. If it appears that an applicant organization does not meet the eligibility requirements, NIH will request a size determination by the SBA. If

eligibility is unclear, NIH will not make an SBIR award until the SBA provides a determination.

Note: An applicant organization that has been determined previously by SBA to be “other than small” for a size standard of not more than 500 employees or for purposes of the SBIR/STTR program, must be recertified by the SBA prior to any future SBIR/STTR awards.

Individuals with the skills, knowledge, and resources necessary to carry out the proposed research are invited to work with their organization to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for NIH support. On an SBIR application, the PD/PI must have his/her primary employment (more than 50%) with the SBC at the time of award and for the duration of the project. For this FOA, the PD/PI transitioning from the academic institution must be primarily employed by his/her research institution at the time of application and must be primarily employed (more than 50% time) by the SBC by or at the time of award. Primary employment with a small business concern precludes full-time employment at another organization. See Section III.1.B for additional requirements. More than one PD/PI (i.e., multiple PDs/Pis) may be designated on the application. Applicant SBCs may submit more than one application, provided each application is scientifically distinct. Applicants may submit a resubmission application, but such application must include an Introduction addressing the previous peer review critique (Summary Statement). See new NIH policy on resubmission (amended) applications (NOT-OD-09-003, NOT-OD-09-016). Only SBIR Phase II awardees are eligible to submit a SBIR Phase II Competing Renewal application, which should represent a continuation of support for research and development of the previous work funded by the original SBIR Phase II grant. SBIR Phase II Competing Renewal applications will be accepted by only those Institutes or Centers described in the current SBIR/STTR Program Descriptions and Research Topics of the NIH, CDC and FDA.

Complete details available at: <http://grants.nih.gov/grants/guide/pa-files/PA-10-122.html>.

■ COMMON PATHOGENETIC MECHANISMS OF LUNG CANCER AND COPD (R01): RFA-HL-11-002

Components of Participating Organizations *National Heart, Lung, and Blood Institute National Cancer Institute*

Letters of Intent Receipt Date(s): May 18, 2010

Application Due Date(s): June 18, 2010

This Funding Opportunity Announcement (FOA) issued by the National Heart, Lung, and Blood Institute and the National Cancer Institute, National Institutes of Health, solicits Research Project Grant (R01) applications from institutions/organizations to identify the fundamental etiopathogenetic commonalities between lung cancer and Chronic Obstructive Pulmonary Disease (COPD) in order to characterize: (a) the genotypic and phenotypic characteristics that determine individual susceptibility; and (b) the shared biochemical, molecular, and immunological pathways involved in the origin and progression of the two diseases.

This FOA will utilize the Research Project Grant (R01) award mechanism. The NHLBI intends to commit up to \$12,000,000 (Total Costs) and the NCI intends to commit up to \$12,000,000 (Total Costs) over 4 years. It is anticipated

that up to 8 awards will be made. The total project period for an application submitted in response to this funding opportunity may not exceed 4 years. Direct costs in each of the years of funding may be up to \$485,000 for applications that do not include a program integrating and coordinating center (PICC, see section I, Research Objectives) and up to \$585,000 direct costs per year for those applications that include a PICC. The amounts will vary depending on the nature of work proposed.

Eligible institutions and organizations include: public or state controlled institutions of higher education; private institutions of higher education; Hispanic-serving institutions; Historically Black Colleges and Universities; Tribally Controlled Colleges and Universities; Alaska native- and native Hawaiian-serving institutions; nonprofit organizations with 501(c)(3) IRS status (other than institutions of higher education); nonprofit organizations without 501(c)(3) IRS status (other than institutions of higher education); small businesses; for-profit organizations (other than small businesses); state governments; Indian/Native American tribal governments (federally recognized); Indian/Native American tribally designated organizations; county governments; city or township governments; special district governments; Independent School Districts; public housing authorities/Indian housing authorities; U.S. territories or possessions; Indian/Native American tribal governments (other than federally recognized); regional organizations; non-domestic (non-U.S.) entities (foreign organizations); eligible agencies of the Federal Government; and faith-based or community-based organizations. Individuals with the skills, knowledge, and resources necessary to carry out the proposed research are invited to work with their institution/ organization to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for NIH support. More than one PD/PI (i.e., multiple PDs/Pis) may be designated on the application. Applicants may submit more than one application, provided each application is scientifically distinct. Resubmission applications are not permitted in response to this FOA. Renewal applications are not permitted in response to this FOA. This FOA uses non-standard due dates.

Complete details available at: <http://grants.nih.gov/grants/guide/rfa-files/RFA-HL-11-002.html>.

■ **NCMHD ADVANCES IN HEALTH DISPARITIES RESEARCH ON SOCIAL DETERMINANTS OF HEALTH (R01): RFA-MD-10-005**

Components of Participating Organizations
National Center for Minority Health and Health Disparities

Application Due Date(s): May 17, 2010

The overarching goal of this FOA is to encourage groundbreaking research addressing the social determinants of health and health disparities. It demonstrates the NCMHD portfolio priority area of interest for ongoing research intervention and information dissemination on the social determinants of health through translational, and transdisciplinary research approaches. The intent of this funding opportunity is to intensify investigator-initiated research, to attract new investigators to the field, and to encourage transdisciplinary research that will advance health disparities science.

This FOA will utilize the NIH Research Project Grant (R01) award mechanism. The NCMHD has designated funding to support approximately 8 or more awards in FY10, contingent

upon the submission of sufficiently meritorious applications. The awards will be made through this offering in 2010. An applicant may request a direct budget cost of up to \$250,000 per year and a project period of up to five years. In addition, Facilities and Administrative (F&A) costs will be provided at the applicant organization's negotiated rates. F&A costs requested by consortium participants are not included in the direct costs limitation (NOT-OD-05-004).

Eligible institutions and organization include: public or state controlled institutions of higher education; private institutions of higher education; Hispanic-serving institutions; Historically Black Colleges and Universities; Tribally Controlled Colleges and Universities; Alaska native- and native Hawaiian-serving institutions; nonprofit organizations with 501(c)(3) IRS status (other than institutions of higher education); nonprofit organizations without 501(c)(3) IRS status (other than institutions of higher education); state governments; Indian/Native American tribal governments (federally recognized); Indian/Native American tribally designated organizations; county governments; city or township governments; special district governments; public housing authorities/Indian housing authorities; U.S. territories or possessions; Indian/Native American tribal governments (other than federally recognized); and faith-based or community-based organizations. Foreign organizations (non-domestic [non-US] entities) are not eligible for this FOA.

Individuals with the skills, knowledge, and resources necessary to carry out the proposed research are invited to work with their institution/ organization to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for NIH support. More than one PD/PI (i.e., multiple PDs/Pis) may be designated on the application. Applicant Institutions/Organizations may submit more than one application, provided each application is scientifically distinct and has a different PD/PI. Resubmission applications are not permitted in response to this FOA.

Renewal applications are not permitted in response to this FOA. This FOA uses non-standard due dates.

Complete details available at: <http://grants.nih.gov/grants/guide/rfa-files/RFA-MD-10-005.html>.

■ **EPIGENETIC FACTORS ASSOCIATED WITH SYMPTOMS AND COMPLICATIONS OF CHRONIC DISORDERS (R01): RFA-NR-10-004**

Components of Participating Organizations
National Institute of Nursing Research

Application Due Date(s): May 17, 2010

The National Institute of Nursing Research (NINR) invites applications to stimulate research that addresses underlying epigenetic factors in symptom expression and complications resulting from chronic disorders. It is anticipated that the findings from this research will help 1) identify individuals at the highest risk for developing severe symptoms and complications secondary to chronic disorders, 2) maximize symptom management, and 3) reduce, prevent, or reverse the occurrence of complications.

This FOA will utilize the R01 award mechanism and runs in parallel with a FOA of identical scientific scope, RFA-NR-10-005, that encourages applications under the Competitive Revision mechanism. A total of \$1.25 M has been committed to this FOA for 2010. It is anticipated that 2–3 R01 awards will be funded. Applicants may propose a maximum of five years of

support and the direct costs cannot exceed \$500,000 for any given year on an R01. Awards issued under this FOA are contingent upon the availability of funds and the submission of a sufficient number of meritorious applications.

Eligible institutions and organizations include: public or state controlled institutions of higher education; private institutions of higher education; Hispanic-serving institutions; Historically Black Colleges and Universities; Tribally Controlled Colleges and Universities; Alaska native- and native Hawaiian-serving institutions; nonprofit organizations with 501(c)(3) IRS status (other than institutions of higher education); nonprofit organizations without 501(c)(3) IRS status (other than institutions of higher education); small businesses; for-profit organizations (other than small businesses); state governments; Indian/Native American tribal governments (federally recognized); Indian/Native American tribally designated organizations; county governments; city or township governments; special district governments; U.S. territories or possessions; Indian/Native American tribal governments (other than federally recognized); regional organizations; non-domestic (non-U.S.) entities (foreign organizations); eligible agencies of the Federal Government; and faith-based or community-based organizations. Individuals with the skills, knowledge, and resources necessary to carry out the proposed research are invited to work with their institution/ organization to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for NIH support. More than one PD/PI (i.e., multiple PDs/Pis) may be designated on the application. Applicants may submit more than one application, provided each application is scientifically distinct. Resubmission applications are not permitted in response to this FOA. Renewal applications are not permitted in response to this FOA. This FOA uses non-standard due dates.

Complete details available at: <http://grants.nih.gov/grants/guide/rfa-files/RFA-NR-10-004.html>.

■ STRATEGIC PARTNERING TO EVALUATE CANCER SIGNATURES [SPECS II] (U01): PAR-10-126

Components of Participating Organizations

National Cancer Institute

Application Receipt Dates: June 15, 2010, June 15, 2011, June 15, 2012

This Funding Opportunity Announcement (FOA), issued by the National Cancer Institute (NCI) of the National Institutes of Health (NIH), encourages the submission of grant applications for support of the clinical application of multi-analyte molecular signatures derived from comprehensive molecular annotation of tumors. There is growing recognition in the clinical cancer research community that annotation of tumor speci-

mens with data that integrates information about molecular alterations at the levels of DNA, RNA, and protein provides not only a more complete understanding of tumor biology but also provides a significant opportunity for developing new clinical tools to improve cancer treatment. Translating the knowledge gained from this molecular annotation into tools that can be used in clinical decision-making remains a major challenge. The purpose of this initiative is to build on recent demonstrations that molecular signatures correlate with important clinical parameters in cancer. The goal of this initiative is also to create publications and data sets that will be available and accessible to the scientific community in order to further the development, design, and conduct of future clinical trials (e.g., incorporation of molecular signatures into future clinical trials and large clinical validation studies) and to encourage appropriate commercialization to benefit the public health. The NCI invites investigators to form strategic partnerships that will bring together the multi-disciplinary expertise and resources needed to determine how the information derived from comprehensive molecular analyses can be used to improve patient care and, ultimately, patient outcomes.

This FOA will utilize the NIH U 01 cooperative agreement mechanism. Awards issued under this FOA are contingent upon the availability of funds and the submission of a sufficient number of meritorious applications. The total project period for an application submitted in response to this funding opportunity may not exceed 5 years.

Eligible institutions and organizations include: public or state controlled institutions of higher education; private institutions of higher education; nonprofit organizations with 501(c)(3) IRS status (other than institutions of higher education); nonprofit organizations without 501(c)(3) IRS status (other than institutions of higher education); small businesses; for-profit organizations (other than small businesses); state governments; regional organizations; non-domestic (non-U.S.) entities (foreign organizations); and eligible agencies of the Federal Government. Individuals with the skills, knowledge, and resources necessary to carry out the proposed research are invited to work with their institution/organization to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for NIH support. More than one PD/PI (i.e., multiple PDs/Pis) may be designated on the application. Applicants may submit more than one application, provided that each application is scientifically distinct. Applicants may submit a resubmission application, but such application must include an Introduction addressing the previous peer review critique (Summary Statement). See new NIH policy on resubmission (amended) applications (NOT-OD-09-003, NOT-OD-09-016). Applicants may not submit a renewal application. This FOA uses non-standard due dates.

Complete details available at: <http://grants.nih.gov/grants/guide/pa-files/PAR-10-126.html>.