
**OMNIBUS SOLICITATION OF THE
NATIONAL INSTITUTES OF HEALTH,
CENTERS FOR DISEASE CONTROL AND PREVENTION,
FOOD AND DRUG ADMINISTRATION, AND
ADMINISTRATION FOR CHILDREN AND FAMILIES FOR**

**SMALL BUSINESS INNOVATION
RESEARCH (SBIR)**

AND

**SMALL BUSINESS TECHNOLOGY
TRANSFER (STTR)**

GRANT APPLICATIONS

**NIH, CDC, FDA, and ACF Program Descriptions and
Research Topics**

SUBMISSION DATES

APRIL 5, AUGUST 5, AND DECEMBER 5, 2012

**(MAY 7, SEPTEMBER 7, 2012 AND JANUARY 7, 2013
FOR AIDS/AIDS-RELATED RESEARCH)**

**National Institutes of Health (SBIR and STTR)
Centers for Disease Control and Prevention (SBIR)
Food and Drug Administration (SBIR)
Administration for Children and Families (SBIR)**

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Funding Opportunity Announcements, Application Instructions, and Appendices are contained in separate files. Follow the links below to view these documents.

FUNDING OPPORTUNITY ANNOUNCEMENTS

REMINDER: ALL APPLICATIONS MUST BE SUBMITTED IN RESPONSE TO A FUNDING OPPORTUNITY ANNOUNCEMENT THROUGH GRANTS.GOV

SMALL BUSINESS INNOVATION RESEARCH PROGRAM PARENT ANNOUNCEMENT (SBIR [R43/R44]) [HTTP://GRANTS.NIH.GOV/GRANTS/GUIDE/PA-FILES/PA-12-088.HTML](http://grants.nih.gov/grants/guide/pa-files/pa-12-088.html)

SMALL BUSINESS TECHNOLOGY TRANSFER PROGRAM PARENT ANNOUNCEMENT (STTR [R41/R42]) [HTTP://GRANTS.NIH.GOV/GRANTS/GUIDE/PA-FILES/PA-12-089.HTML](http://grants.nih.gov/grants/guide/pa-files/pa-12-089.html)

ADDITIONAL SPECIAL ANNOUNCEMENTS FOR SMALL BUSINESS RESEARCH OPPORTUNITIES
[HTTP://GRANTS.NIH.GOV/GRANTS/FUNDING/SBIR_ANNOUNCEMENTS.HTM](http://grants.nih.gov/grants/funding/sbir_announcements.htm)

APPLICATION INSTRUCTIONS

SF424 (R&R) APPLICATION INSTRUCTIONS AND ELECTRONIC SUBMISSION INFORMATION
([HTTP://GRANTS.NIH.GOV/GRANTS/FUNDING/424/INDEX.HTM](http://grants.nih.gov/grants/funding/424/index.htm))

APPENDICES

STTR MODEL AGREEMENT ([MS WORD](#))

EXTRAMURAL INVENTION REPORTING COMPLIANCE RESPONSIBILITIES ([HTTPS://S-EDISON.INFO.NIH.GOV/IEDISON/TIMELINE.JSP](https://s-edison.info.nih.gov/iedison/timeline.jsp))

PROGRAM DESCRIPTIONS AND RESEARCH GRANT TOPICS

The research topics shown in this solicitation represent program areas that may be of interest to applicant small business concerns in the development of projects that have potential for commercialization. Small business concerns are encouraged to submit SBIR/STTR grant applications in these areas.

APPLICABLE TO NIH ONLY: SBIR and STTR grant applications will be accepted and considered in any area within the mission of the awarding components (i.e., Institutes and Centers (ICs)) identified in this solicitation.

Applicants are strongly encouraged to subscribe to the NIH Guide for Grants and Contracts LISTSERV (<http://grants.nih.gov/grants/guide/listserv.htm>) or query program administrators periodically via email to learn of new or emerging scientific interests of the NIH, CDC, FDA, and ACF awarding components.

You may also subscribe to the SBIR-STTR LISTSERV list to get timely information about the NIH SBIR/STTR Programs (<http://grants.nih.gov/grants/funding/listserv.htm>).

Additional information on each of the awarding components (ICs) and their research interests is available electronically on the home pages shown throughout the "Research Topics" section of the solicitation.

The Fogarty International Center, which provides support only for conferences, postdoctoral fellowships for research in the United States and abroad, and senior scientist exchanges between the United States and other countries, does not participate in the SBIR/STTR program.

NATIONAL INSTITUTES OF HEALTH (NIH)

NIH is the steward of medical and behavioral research for the Nation. Its mission is science in pursuit of fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce the burdens of illness and disability.

The goals of the agency are as follows:

1. to foster fundamental creative discoveries, innovative research strategies, and their applications as a basis for ultimately protecting and improving health;
2. to develop, maintain, and renew scientific human and physical resources that will assure the Nation's capability to prevent disease;
3. to expand the knowledge base in medical and associated sciences in order to enhance the Nation's economic well-being and ensure a continued high return on the public investment in research; and
4. to exemplify and promote the highest level of scientific integrity, public accountability, and social responsibility in the conduct of science.

In realizing these goals, the NIH provides leadership and direction to programs designed to improve the health of the Nation by conducting and supporting research:

- in the causes, diagnosis, prevention, and cure of human diseases;
- in the processes of human growth and development;
- in the biological effects of environmental contaminants;
- in the understanding of mental, addictive and physical disorders; and
- in directing programs for the collection, dissemination, and exchange of information in medicine and health, including the development and support of medical libraries and the training of medical librarians and other health information specialists.

In addition, the NIH sponsors training of research personnel; career development of new and established scientists; construction and renovation of research facilities and provision of other research resources.

To carry out these responsibilities, the NIH is organized into awarding components (Institutes/Centers). Those components that have an extramural element, that is, provide funds for research and research training activities in organizations external to the NIH, are shown below. The NIH makes every effort to finance worthy applications, including the co-funding of such applications by one or more awarding components having relevance in the projects.

Funding levels for projects are determined through the combined interaction among peer review, grants management, program, budget, and other Institute and/or Centers (IC) staff. These levels are based on allowable costs that are consistent with the principles of sound cost management and in consideration of IC priorities, constraints on the growth of average grant costs, and the availability of funds.

TRANS-NIH RESEARCH PROGRAMS

Phase IIB Competing Renewal Awards

Some NIH Institutes/Centers (ICs) offer Phase II SBIR/STTR awardees the opportunity to apply for Phase IIB Competing Renewal awards. These are available for those projects that require extraordinary time and effort in the R&D phase and may or may not require FDA approval for the development of such projects, including drugs, devices, vaccines, therapeutics, and medical implants related to the mission of the IC. Some ICs have announced this opportunity through the NIH Guide for Grants and Contracts (see link below), and some are using this Omnibus SBIR/STTR Grant Solicitation. Only those small business concerns who have been awarded a Phase II are eligible to apply for a Phase IIB Competing Renewal award. Prospective applicants are strongly encouraged to contact NIH staff prior to submission. Additional requirements and instructions (e.g., submission of a letter of intent) are available in the specific IC research topics section and in the specific [IC Program Funding Opportunity Announcements](http://grants.nih.gov/grants/funding/sbir_announcements.htm) (http://grants.nih.gov/grants/funding/sbir_announcements.htm). The following NIH ICs will accept applications for Phase IIB Competing Renewal awards: **NIA**, **NIAAA**, **NIAID** (SBIR only), **NICHD** (SBIR only and only Competing Renewals of NICHD-supported Phase II awards), **NIDA**, **NIDCD**, **NIDDK** (only Competing Renewals of NIDDK-supported Phase II awards), **NEI** (SBIR only), **NIGMS** (SBIR only), **NIMH** (SBIR only), **NCATS** (SBIR only), and **ORIP** (SBIR only). NCI offers Phase IIB opportunities that focus on the commercialization of SBIR-developed technologies. Contact the NCI SBIR Development Center at 301-594-7709, NCISBIR@mail.nih.gov for additional information. NHLBI will offer Phase IIB Competing Renewal opportunities that focus on the commercialization of technologies requiring regulatory approval (contact Kurt Marek, Ph.D., at 301-443-8778 or kurt.marek@nih.gov for additional information). 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 NINDS SBIR webpage: http://www.ninds.nih.gov/funding/small-business/small_business_funding_opportunities.htm.

Research Supplements to Promote Diversity in Health-Related Research

(See Funding Opportunity Announcement at <http://grants.nih.gov/grants/guide/pa-files/PA-08-190.html>.)

The NIH recognizes a unique and compelling need to promote diversity in the biomedical, behavioral, clinical and social sciences research workforce. The NIH expects efforts to diversify the workforce to lead to the recruitment of the most talented researchers from all groups; to improve the quality of the educational and training environment; to balance and broaden the perspective in setting research priorities; to improve the ability to recruit subjects from diverse backgrounds into clinical research protocols; and to improve the Nation's capacity to address and eliminate health disparities.

The NIH notifies Principal Investigators holding specific types of NIH research grants (including SBIR and STTR awards) that funds are available for administrative supplements to improve diversity by supporting and recruiting students, postdoctorates, and eligible investigators from groups that have been shown to be underrepresented in the biomedical, behavioral, clinical, and social sciences research workforce. Although the administrative supplements supported under this program provide funding for less than one percent of all individuals involved in NIH supported research, the NIH has found these awards to be an effective means of encouraging institutions to recruit from currently underrepresented groups. Administrative supplements must support work within the scope of the original project.

All NIH awarding components and the National Institute for Occupational Safety and Health at the CDC participate in this program. Candidates eligible for support under this supplement program include individuals at various career levels who come from groups that have been shown to be underrepresented in science. Such candidates include individuals from underrepresented racial and ethnic groups, individuals with disabilities, and individuals from disadvantaged backgrounds. Detailed eligibility criteria are described in the full announcement.

An application for a supplement may be submitted at any time. In making requests, the grantee institution, on behalf of the Principal Investigator of the parent grant and in cooperation with the candidate **must submit the application for supplemental funds directly to the awarding component that supports the parent grant. The application must not be submitted through grants.gov or to the NIH Center for Scientific Review.**

Requests for administrative supplements can be submitted to the NIH Program Official listed in the contacts section of the FOA [PA-08-190](#) at any time. Administrative supplements normally end with the competitive cycle of the parent grant

TECHNICAL ASSISTANCE PROGRAMS (SUBJECT TO CHANGE)

Available to NIH SBIR Awardees

(Note that STTR Awardees are not eligible for these programs)

One of the goals of the Small Business Innovation Research (SBIR) program is to “increase private sector commercialization of innovations developed through Federal SBIR R&D.” To help NIH SBIR awardees move their products into the marketplace, NIH has developed several assistance programs that provide technical and/or commercialization assistance specific to the individual needs of NIH SBIR awardees.

Additional information about these programs is available at <http://grants.nih.gov/grants/funding/tap.htm>. Questions may be addressed to the NIH SBIR Office at sbir@od.nih.gov.

Niche Assessment Program

(For NIH SBIR Phase I awardees)

The Niche Assessment program focuses on obtaining the necessary information for strategizing and making deals. Often, a research scientist does not have the entrepreneurial skills to assess whether there are other applications or market niches for their SBIR-developed technology. As a result, they may underestimate its true market value. This program assesses the market opportunities, needs and concerns of end-users and helps to discover new markets for possible entry for the SBIR-developed technology. With the assistance of the participant, a contractor helps identify niches and potential partners. The contractor performs the due diligence and provides an in-depth report that assesses such items as the potential end-users needs, the competing technologies and products, the competitive advantage, the market size and share that the participant might expect, etc. Targets (end users) are contacted to ensure they are viable leads and their contact information is included in the report for possible follow-up. Participants may find this report helpful in preparing the requisite Commercialization Plan for a Phase II application. For detailed information about the Niche Assessment Program, see <http://grants.nih.gov/grants/funding/nap.htm>.

Participation in this program is limited to NIH SBIR Phase I awardees (grants and contracts) and participants need only commit a few hours to inform and make the contractor fully conversant on their technology and the niche they would like to have investigated. There is no cost to the NIH SBIR awardee to participate in this program.

**Commercialization Assistance Program (CAP)
(For NIH SBIR Phase II awardees)**

The Commercialization Assistance Program (CAP) assists small companies with getting their SBIR-developed technologies more rapidly into the marketplace. It provides assistance with developing and implementing an appropriate business strategy aimed at commercializing the products or services that have resulted from NIH-supported SBIR awards.

CAP can include two distinctive tracks that offer customized assistance to meet the specific needs of both early stage and seasoned companies: (1) Commercialization Training Track (CTT), and in some years (2) Accelerated Commercialization Track (ACT). CTT is aimed at assisting participants with evaluating their commercialization options based on their specific technologies and to develop a solid market-entry plan covering an 18-month period. It also assists in the development of market-appropriate tools to accomplish these objectives.

The ACT track assists those companies that may have successfully commercialized products and/or services, generated revenue, established partnerships and/or otherwise achieved a level of market development that is sustainable over a definitive period. However, they may be lacking in a specific, applicable issue (such as a solid regulatory plan, a license-focused IP strategy or a term sheet for investors), whose resolution is key to their continued growth.

Participation in CAP is limited to NIH SBIR Phase II awardees (grants and contracts) from the previous five years. Applications to participate are typically accepted in early summer. Participation is free to the NIH SBIR awardee; however, participants are responsible for travel and lodging expenses associated with attending workshops and partnering investment events. Detailed information is available at <http://grants.nih.gov/grants/funding/cap/index.htm>.

NIH, CDC, FDA, AND ACF AWARDED COMPONENT CONTACT INFORMATION

AWARDING COMPONENT	PROGRAM CONTACT	GRANTS MGMT. CONTACT
National Institute on Aging http://www.nia.nih.gov	Dr. Michael-David A.R.R. Kerns Phone: 301-402-7713 Fax: 301-402-2945 Email: Michael-David.Kerns@nih.gov	Ms. Linda Whipp Phone: 301-496-1472 Fax: 301-402-3672 Email: Linda.Whipp@nih.gov
National Institute on Alcohol Abuse and Alcoholism http://www.niaaa.nih.gov	Dr. Gary Murray Phone: 301-443-9940 Fax: 301-594-0673 Email: Gary.Murray@nih.gov	Ms. Judy Fox Phone: 301-443-4704 Fax: 301-443-3891 Email: Judy.Fox@nih.gov
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AWARDING COMPONENT	PROGRAM CONTACT	GRANTS MGMT. CONTACT
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<p>Administration for Children and Families http://www.acf.hhs.gov</p>	<p>Anne F. Bergan Phone: 202-260-8515 Fax: 202-205-3598 Email: abergan@acf.hhs.gov</p>	<p>Edeltraud Fernandez Phone: 202-401-2346 Fax: 202-205-3598 Email: efernandez@acf.hhs.gov</p>

NATIONAL INSTITUTE ON AGING (NIA)

The NIA SBIR-STTR Programs support biomedical, behavioral, and social research and research training on the aging process as well as on the diseases and other special problems and needs of older people. It supports SBIR and STTR grant research under four established divisions: Behavioral and Social Research, Aging Biology, Geriatrics and Clinical Gerontology, and Neuroscience.

Examples of research topics within the mission of the NIA that may be of interest to small businesses are shown below. These listings illustrate the range of areas that are of interest to the NIA and are not intended to be exhaustive.

For additional information about areas of interest to the NIA, please visit our home page at <http://www.nia.nih.gov>.

Phase IIB Competing Renewal Awards

NIA accepts Phase IIB Competing Renewal grant applications from Phase II SBIR/STTR awardees to continue the process of developing products, primarily for pharmaceutical compounds and medical devices, requiring regulatory approval by the Food & Drug Administration (FDA). NIA will accept applications for up to two (2) years and up to \$750,000 per year in total costs. The Phase IIB Competing Renewal award is intended to allow small businesses the opportunity to advance research to a stage where interest in and investment by third parties would be more likely.

Prospective Phase IIB Competing Renewal applicants are strongly encouraged to submit a letter of intent to Dr. Kerns that includes the following information:

- Descriptive title of the proposed research
- Name, address, and telephone number of the Principal Investigator
- Names of other key personnel
- Anticipated Budget
- Participating institutions
- Funding Opportunity Announcement Number (e.g., PA-12-XXX, if relevant)

Although a letter of intent is not binding and does not enter into the review of a subsequent application, it allows NIA staff to estimate the potential review workload, plan the review, and consider budget implications. It is anticipated that only a small number of NIA SBIR/STTR Phase II awards would be eligible for a Phase IIB Competing Renewal award.

The following examples would make appropriate topics for Phase IIB Competing Renewal projects. These are meant only as indications of potential Phase IIB Competing Renewal projects and are not exclusive of other appropriate activities. Research and development efforts can be focused, for example, on medications to treat, delay the progression of or prevent age-related cognitive decline, mild cognitive impairment (MCI), Alzheimer's disease, and other dementias of aging.

1. Studies for preclinical discovery and development of drugs, natural products, or other types of compounds, including pharmacology and toxicology studies, beyond those conducted under the initial SBIR Phase I and Phase II grants. The studies conducted under the previous grants should be sufficient to provide a sound rationale for continued development of the compound, drug or natural product.
2. Completion of studies as required by the FDA for an IND application.
3. Human clinical trials/studies to determine a drug's, natural product's, or other type of compound's safety profile, metabolism, and/or efficacy.

For questions relating to Phase IIB Competing Renewal applications, please contact:

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Division of Behavioral and Social Research (DBSR)

Basic and translational social and behavioral research on aging processes and the place of older people in society. The division focuses on how people change with age, on the interrelations between older people and social institutions (e.g., the family, health-care systems), and on the societal impact of the changing age-composition of the population. Special emphasis areas are (1) Health Disparities; (2) Aging Minds; (3) Increasing Health Expectancy; (4) Health, Work, and Retirement; (5) Interventions and Behavior Change; (6) Genetics, Behavior, and the Social Environment; and (7) the Burden of Illness and the Efficiency of Health Systems.

In the past, DBSR has supported development of training videos (including interactive internet-based training) for programs or interventions and development of medication reminder devices through the SBIR-STTR grant mechanism. DBSR currently has minimal interest in development of new training videos or internet based training (especially for programs or interventions that have not been subjected to rigorous evidence-based evaluation) or in the development of medication-reminder devices (without clear demonstration that a new & previously unidentified market of public-health importance would be served).

- A. Social, behavioral, environmental and or/technical interventions on the individual, institutional, family, community or national level intended to maintain older adult independence or functioning, increase well-being and prevent disease and/or disability.
 - 1. Interventions to remediate age-related cognitive decline, especially using technology platforms with wide acceptance among older adults;
 - 2. Interventions directed at self-management of chronic diseases among the elderly, including behavioral change and applications to enhance compliance;
 - 3. Interventions to enhance social function or to improve physical and psychological well-being in midlife and older age;
 - 4. The development of evidence-based, risk-reduction programs (also referred to as health promotion, health management, demand management, and disease-prevention programs) that are applicable to older U.S. workers.
- B. Interventions or programs for issues impacting caregivers of the elderly and older individuals needing long-term care.
 - 1. Development of strategies for care providers (both professionals and families) to deal with burdens associated with chronic disabling illness or disease (including Alzheimer’s disease);
 - 2. Programs or interventions that address/decrease the trauma and difficulty of elders, their families, and care providers faced with end of life decisions and events that surround the end of life.
- C. Genetics and Genome Wide Association
 - 1. Development of innovative methods and software to facilitate analysis of personal data linked to geocoded data, biological, cognitive or genetic measures, with improved protection for confidentiality.
 - 2. Develop online genetic counseling so that users have a way to interface with professionals regarding issues that may have arisen after learning about genetic risk for disease, or about any new ancestry information that might be at odds with their self-identified race.

3. Develop a more targeted understanding of who will engage in DTC genetic testing and who will not, based on personality and other characteristics. This could be accomplished through comparisons with other large-scale surveys.

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- D. The development of software to improve financial decision making among older people. The software should include projected retirement earnings and expenditures on long term care and out of pocket medical expenditures.
- E. The development of practical applications using innovative technologies (e.g. hand-held, internet, telemedicine GPS, robotics, social networking and communications technologies) to support and improve quality of life, well-being, and the ability of older adults to live independently and safely at home.
- F. New sampling and data collection methodologies for use in large population-based household surveys and behavioral interventions of relevance to aging. These include:
 1. Experience sampling and new devices for real-time collection of data;
 2. Performance based measures for cognitive or physical functioning as well as new instruments for cognitive testing, sleep quality, assessment of basic decision-making domains, or assessments of social behaviors;
 3. Improvements to blood spot technology for biological data collection (this includes the development of multiple and reliable assays for limited blood spot specimens).
- G. Survey Development/Archiving/Database support
 1. Development of new databases and database support infrastructure to satisfy data and research needs in aging as well as the development of innovative data archives to make current statistical and epidemiological data more accessible and policy relevant;
 2. Development of data extraction web tools for public use databases;
 3. Development of innovative methods and software to provide improved access to complex longitudinal studies or surveys that cannot be placed in open data archives because of issues relating to confidentiality;
 4. Development of innovative methods and software to facilitate analysis of personal data linked to geocoded data, biological, cognitive or genetic measures, with improved protection for confidentiality of respondents;
 5. Development of data infrastructure and tools for assessing the economic impact of federally-funded research.
- H. Forecasting and Software for analyzing of healthcare claims
 1. Development of models that will lead to improved forecasting of national, state and county level estimates of the demand for aging-related services; and improved prediction of the costs and effects of public health interventions, changes in health-care financing and insurance, social security, pension coverage or changes in the retirement age. Both domestic and international projections are of interest;
 2. Development of software which will provide insight on key factors that contributes to growth of medical expenditures through analysis of claims data.

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Division of Aging Biology (DAB)

DAB sponsors research on the molecular, cellular, genetic, and physiological causes and consequences of aging processes. The ultimate goal is to develop interventions to reduce and/or delay age-related degenerative processes in humans. DAB also has responsibility for maintaining existing resources and developing new resources for aging research, such as populations of well-characterized animals and specific cell lines including, for example, human fetal lung fibroblasts.

DAB areas of research that may be of interest to small businesses include, but are not limited to:

- A. Effects of metabolism on the aging process, e.g., how metabolic regulation influences longevity, and the development of anti-oxidants or other interventions to reduce oxidative stress and aging-related diseases.

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- B. Development of minimally-perturbing techniques for collecting blood from mice, rats, and other animals several times a day in sufficient quantities for measurement of hormone levels and other circulating factors in young and old animals, or development of non-invasive research and test methods for use in animals.

Dr. Nancy Nadon
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- C. Development of molecular probes such as antibodies, DNA sequences and expression vectors useful in studying aging, senescence, and longevity both *in vivo* and *in vitro*.

Dr. Rebecca Fuldner
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- D. Development of new animal models, including transgenic animals, for studying aging processes, as well as development of new biological model systems for research on aging to replace or reduce vertebrate animal use in research. These models may include better *in vitro* systems, improved cell culture methods, mathematical models, and computer simulations.

Dr. Mahadev Murthy
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- E. Development of interventions to slow down the degenerative processes associated with aging. These would include techniques with commercial potential to: (1) manipulate the control of cell proliferation or programmed cell death, (2) reduce the level of damage to nucleic acids, proteins and lipids and the macromolecular complexes formed from these molecules, (3) improve the damage surveillance and repair potential of cells, (4) improve the immune response to foreign molecules or reduce the response to self, and (5) reverse age-related changes in hormone production and function.

Dr. Nancy Nadon
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- F. Development of treatments for wound healing in the aged. These would include devices, processes, and pharmacological agents with the potential to (1) promote wound healing in aged tissues such as

skin, muscle, cartilage, and bone, or (2) reduce scar formation without compromising effective healing. Wounds produced by accidental damage or resulting from surgery would be appropriate for consideration.

Dr. John Williams

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- G. Development of cell-based therapies or other treatments to repair myocardial or vascular tissues after ischemia. The work should include consideration of age-related effects on the therapy or treatment.

Dr. Ronald Kohanski

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- H. 1. Development of tools and technologies to characterize cellular heterogeneity in aging tissues at the single cell level.
2. Development of interventional strategies to alter the senescence status of cells in tissues and organs of old animals.
3. Development of computational and bio statistical methods for systems biology approaches.

Dr. Jose Velazquez

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- I. Development of tools, methods, resources, biomarkers, and interventions in the areas of genetics, epigenetics, genomics, functional genomics, bioinformatics, computational biology, telomere, and DNA repair:
1. Development of tools and resources in genetics and genomics to study molecular mechanisms of normal aging or aging-related diseases.
2. Development of biomarkers for prognosis, diagnosis, or treatment monitoring of aging or aging-related diseases. Biomarkers of sufficient reliability, sensitivity and specificity are likely to be comprised of multiple physiological parameters, rather than a single molecular entity. Biomarker signatures may be composed of multiple genes, RNAs, microRNAs, proteins, or metabolites, or combinations thereof. Approaches using genomics, epigenomics, transcriptomics, proteomics, metabolomics, lipomics, glycomics, or other high throughput measurements are encouraged to develop such biomarkers or biomarker signatures.
3. Development of computational, statistical, or bioinformatics tools and resources to manage, integrate, and mine high throughput data obtained by genomic, functional genomic or other 'omic" approaches.
4. Development of databases, methods for integration of databases, or data analysis systems for aging research.
5. Development of technologies, tools, methods, and resources useful for systems biology study of aging and aging-related diseases.

Dr. Max Guo

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Division of Neuroscience (DN)

DN supports research on age-related changes in the brain or nervous system in the context of other age-related physiological or homeostatic regulator changes (e.g., endocrine, dietary, sleep and circadian rhythms, immune, disease states); degenerative processes or pathological changes in the aging brain in the context of understanding normal age-related changes; and the sensory, motor, perceptual and cognitive processes and changes that occur with aging as related to their underlying biological mechanisms.

An important component of DN is the support of studies on Mild Cognitive Impairment (MCI), Alzheimer's disease (AD), and other dementias of aging such as Frontotemporal Dementia, Lewy Body Dementia, and Vascular Dementia.

Areas that may be of interest to small businesses include, but are not limited to:

- A. Development of sensitive, specific and standardized tests for diagnostic screening of cognitive decline and dementia; for example, the development of novel neuropsychological, biochemical and neuroimaging methods for the early detection of cognitive decline and MCI and the early diagnosis of AD.

Dr. John Hsiao
301-496-9350; Fax: 301-496-1494
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or

Dr. Nina Silverberg (neuropsychological detection methods)
Email: silverbergn@mail.nih.gov

- B. Discovery, development, and/or evaluation of drugs, biological or natural products, including central-nervous-system delivery systems, to enhance cognitive functioning in normal aging and to treat the cognitive deterioration and/or behavioral symptoms associated with MCI, AD, and other dementias of aging as well as to slow and/or reverse the course of the disease or to prevent it entirely.

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and

Dr. Suzana Petanceska (MCI, AD, & other dementias of aging)
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and

Dr. Molly Wagster (Cognitive functioning in normal aging)
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The development of practical applications using innovative technologies (e.g. hand-held, internet, telemedicine GPS, robotics, social networking and communications technologies) to support and improve quality of life, well-being, and the ability of people with MCI, AD or other dementias of aging to live independently and safely at home for an extended period of time. Examples include systems and devices to: evaluate, monitor and improve or adapt to changes in cognition; improve health service delivery; support independent living and the conduct of everyday tasks at home; provide information to health care providers and family members with which to evaluate the need for intervention; and promote

communication and interaction between individuals living in the community or in institutional settings and their health care providers, friends and family members.

Dr. Nina Silverberg

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- C. Testing in clinical trials of drug, nutritional, behavioral, cognitive or other types of interventions to enhance cognitive functioning in normal aging and to treat cognitive deterioration and/or behavioral symptoms associated with MCI, AD, and other dementias of aging as well as to slow and/or reverse the course of disease or to prevent the onset of disease.

Dr. Laurie Ryan (MCI, AD, & other dementias of aging)

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Dr. Molly Wagster (Cognitive functioning in normal aging)

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- D. Devices or intervention strategies that may prolong functional independence when there are dysfunctions of the central nervous system.
- E. Behavioral, environmental, pharmacological, & nutritional interventions to prevent and/or remediate brain biochemical and/or neurophysiological changes caused by normal aging and neurodegenerative diseases, including age-related sensory dysfunction (e.g., pain, hearing loss, speech communication disorders, olfaction loss, & vision loss), motor dysfunctions (including Parkinson's disease & other age-related psychomotor disorders) or age-related decrements in balance & postural control, gait performance, and mobility.
- F. Biosensors and prosthetic devices, technologies, and related software development to aid in the assessment, diagnosis, and remediation of age-related cognitive decline or sensory dysfunction (including pain), motor dysfunction (including Parkinson's disease and other motor disorders of aging), or age-related changes in balance, postural control, and gait. Novel markers of normal age-dependent cognitive decline or sensory and/or motor system changes at the molecular cellular, circuitry, physiological or behavioral level in humans or relevant animal models.

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or

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- G. New technologies to screen for the presence of sleep disorders in older persons, to aid in the diagnosis of these disorders, and to enable their remediation.
- H. Minimally invasive technologies to detect prion diseases early in the course of the disease process in older adults, as well as effective treatment strategies to slow, halt or prevent these diseases.

Dr. Miroslaw Mackiewicz

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- I. Improved instrumentation, imaging technology, related devices, and software packages for use in visualizing neural activity during cognitive or sensory behavior in older adults. Also of interest would be new technologies to combine neural imaging and behavioral assessment in awake animals.

Dr. Molly Wagster

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- J. Development of technology and analysis tools to examine cellular patterns of gene and protein expression in the normal and diseased aging nervous system, including the identification of aberrant gene products expressed in the aging brain. Development of molecular imaging technology for the *in vitro* and *in vivo* analysis of gene and protein function in the normal aging brain and in the diseased aging nervous system.
- K. Development of technology, including non-invasive methods and novel probes, to monitor and manipulate the plasticity of neural circuits in the adult and aged nervous system. Development of novel markers of neural stem cell function (proliferation, migration, and differentiation) as well as methods to assess the integration and function of stem cells in the nervous system.

Dr. Brad Wise (Normal brain aging)

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and

Dr. Lawrence Refolo (Alzheimer's disease & other dementias of aging)

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Division of Geriatrics and Clinical Gerontology (DGCG)

DGCG supports clinical and translational research on health and disease in the aged and research on aging over the human life span and its relationships to health outcomes. Translational research is of interest for developing and testing the effectiveness of interventions known to be efficacious for everyday clinical practice and health decision making. Research on Geriatrics focuses primarily on health issues regarding the aged, and deals with research on disease and disability in older persons, including both specific conditions and issues related to multiple morbidity. Clinical Gerontology Research focuses primarily on clinically related issues regarding aging, and deals with research on aging changes over the life span. A major focus is on the determinants of rates of progression of age-related changes that affect disease risk, particularly those affecting risk for multiple age-related conditions.

Areas of interest include but are not limited to:

- A. Development of vaccines and other agents for preventing and treating infections in older persons, including development of new vaccines or preventive interventions, and new methods using currently available vaccines or preventive medications.
- B. Development of clinical decision support tools that helps physicians caring for patients with multiple chronic conditions to prioritize the interventions that are most beneficial and relevant within the context of these patients' lives.
- C. Devices and/or techniques for preventing or treating urinary incontinence.
- D. Development of improved post-surgical treatments/technologies promoting wound healing and reduced scar formation.

Dr. Marcel Salive

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- E. Refinements in techniques for the measurement of age-related changes in hormone levels, status or pharmacokinetics (e.g., those of growth hormone, IGF-1 and its binding proteins; estrogen, progesterone, testosterone; other markers of ovarian, testicular, hypothalamic and pituitary function). The objective is to enhance sensitivity and achieve greater economy in the assay cost.
- F. Effects of menopause on woman's aging and subsequent health. Effects of age-related changes in endocrine status in men on subsequent aging, morbidity and mortality.
1. Refinements in techniques for the measurement of age-related changes in hormone levels or pharmacokinetics (e.g., those of growth hormone, IGF-1 and its binding proteins; estrogen, progesterone, testosterone; other markers of ovarian, testicular, hypothalamic and pituitary function).
 2. Development and testing of alternative strategies (to conventional estrogen/ progestin therapy) for the management of short-term menopausal symptoms and for the reduction in risks of cardiovascular disease, osteoporosis, and other menopause-related conditions, disorders and diseases. Development and testing of new tissue-specific modulators of estrogen/ androgen receptor activity in men and in women for the prevention or treatment of age-related diseases.
 3. Development, testing and validation of new surrogate measures of clinically relevant outcomes and endpoints (e.g., fractures) for (1) more immediate and accurate assessment of the risk or progression of age-related diseases (e.g., osteoporosis) or (2) to predict or monitor efficacy of treatment or enhanced risk or progression of adverse effects/events.
 4. Determine drug interactions, i.e., potential alterations in pharmacokinetics and pharmacodynamic properties of drugs taken concomitantly with postmenopausal hormones.
- G. Osteoporosis. Development, testing, and validation of new surrogate measures of clinically relevant outcomes and endpoints (e.g., fractures) for (1) more immediate and accurate assessment of the risk or progression of age-related diseases (e.g., osteoporosis) or (2) to predict or monitor efficacy, response to treatment or enhanced risk or progression of adverse effects/events.
- Development and validation of non-invasive methods of examining bone quality (density, architecture, and strength of bone).

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- H. Improved instrumentation and imaging techniques for measuring body composition and properties such as muscle function in older persons.
- I. Development of techniques/devices (e.g., non-invasive, portable) for improved monitoring of caloric intake and/or energy expenditure in epidemiological studies.

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- J. Measuring ambulation and assessing factors contributing to problems in and/or related to ambulation and mobility in general
1. Development of improved instrumentation for biomechanical assessment of ambulation and falls.
 2. Development of improved instrumentation to assess balance, sway, gait, and postural control to identify stable and unstable patterns of movement during activities of daily living

3. Development of improved quantitative methods of assessing postural perturbations relevant to activities of daily living.
- K. Development of improved, lightweight, and absorbent materials or other interventions to prevent, protect against and minimize injuries suffered from falls.
- L. Development of assistive technologies to enable and support older persons to live independently and safely at home
1. Development of devices/assistive technologies addressing complications of limited mobility among older persons.
- M. Development of technologies to assist in the improvement of physical function and mobility in older persons prior to (prehabilitation) or following (rehabilitation) elective/planned surgery.
- N. Research on better ways to prevent injuries and deaths associated with the use of currently-available bed rails in populations of older patients. Such research would include work on their identification and testing of improved designs of bed systems for use in homes, skilled nursing facilities, and hospitals.
- Dr. Lyndon Joseph
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- O. Development of devices and techniques for screening substantial numbers of individuals for particular alleles at loci of relevance to human genetic studies of aging.
- P. Development and validation of imaging and sensor technologies to improve measures of physiologic changes with age.
- Ms. Winifred Rossi, M.A.
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- Q. Development and validation of improved approaches for evaluation, monitoring or treatment of diastolic dysfunction in older adults.
- R. Development and validation of improved techniques for hemodynamic monitoring of older adults in emergency and/or critical care settings.
- S. Development and validation of instruments or methods to evaluate fatiguability—the level of fatigue related to the intensity, duration, and/or frequency of activity (in contrast to measures of fatigue), particularly in adults with or at-risk of developing age-related conditions or diseases leading to physical disability.
- T. Development and validation of innovative approaches to pain control that consider age-related physiologic changes such as gastrointestinal absorption, cutaneous integrity, and musculoskeletal structure and function.
- U. Development and evaluation of treatment approaches to age-related diseases or conditions based on modulation of the thyroid hormone axis.
- V. Interventions and methods for screening, diagnosis, and treatment of cancer in older persons.
- W. Development of methods to accurately determine the renal glomerular filtration rate (GFR) in older persons and patients with chronic kidney disease. The new methods should justify the effects of age-related changes in muscle mass, levels of serum creatinine, renal blood flow and renal concentrating ability.
- X. Identification of novel biomarkers of acute kidney injury and chronic kidney disease in older persons. Such research would include identification of biomarkers and evaluation of their clinical utility for

early diagnosis, prediction of the course of progression of diseases and/or monitoring the effects of treatment.

- Y. Development and validation of new technology such as non-invasive methods to examine blood-flow velocity in arteries, individual coronary arteries, renal arteries, and cerebral arteries.

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For additional information on research topics and administrative questions, contact:

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NATIONAL INSTITUTE ON ALCOHOL ABUSE AND ALCOHOLISM (NIAAA)

NIAAA supports research on the causes, prevention, control, and treatment of the major health problems associated with alcohol use. Through its extramural research programs, NIAAA funds a wide range of basic and applied research to develop new and/or improved technologies and approaches for increasing the effectiveness of diagnosis, treatment, and prevention. NIAAA also is concerned with strengthening research dissemination, scientific communications, public education, and data collection activities in the areas of its research programs.

In addition to Phase I studies in the pursuit of the above aims, NIAAA will also accept Phase II and Phase IIB applications. For additional information about areas of interest to the NIAAA, you are invited to visit our home page at <http://www.niaaa.nih.gov>.

Limited Amount of Award

For budgetary, administrative, or programmatic reasons, NIAAA may decrease the length of an award and/or the budget recommended by a review committee, or not fund an application. Generally, NIAAA does not fund Phase I applications greater than \$300,000 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

NIAAA will accept SBIR/STTR Phase IIB Competing Renewal grant applications from Phase II SBIR/STTR awardees to continue the process of developing products that require approval of a Federal regulatory agency (e.g., FDA, FCC). Such products include, but are not limited to, medical implants, drugs, vaccines, and new treatment or diagnostic tools that require FDA approval. This renewal grant should allow small businesses to get to a stage where interest and investment by third parties is more likely.

Please contact Dr. Gary Murray (contact information provided below) before beginning the process of putting an application together. Prospective applicants are strongly encouraged to contact NIH staff prior to submission of a Competing Renewal application. Prospective applicants are strongly encouraged to submit to the program contact a letter of intent that includes the following information:

- Descriptive title of the proposed research
- Name, address, and telephone number of the Principal Investigator
- Names of other key personnel
- Participating institutions
- Funding Opportunity Announcement Number (e.g., PA-12-XXX)

Although a letter of intent is not required, is not binding, and does not enter into the review of a subsequent application, the information that it contains allows NIH staff to estimate the potential review workload and plan the review. It is expected that only a portion of NIAAA SBIR/STTR Phase II awards will be eligible for a Phase IIB Competing Renewal grant.

The following examples would make appropriate topics for proposed SBIR or STTR Phase IIB Competing Renewal projects.

These examples are meant for illustrative purposes and are not exclusive of other appropriate activities:

- Preclinical studies, including pharmacology and toxicology, beyond those conducted under the Phase I (R43) and initial Phase II (R44) grants. Some *in vivo* or *in vitro* studies would be expected to have been carried out in Phase I or the initial Phase II grant.
- Completion of studies as required by the Food and Drug Administration (FDA) for Investigational New Drug (IND) or Radioactive Drug Research Committee (RDRC) application
- Development and clinical evaluation of new alcohol-sensitive biomarkers
- Assessment of devices with regard to performance standards related to the FDA approval process
- Safety and effectiveness studies of novel medical devices
- Biocompatibility studies of surface materials of putative medical implants
- Evaluation of novel imaging approaches for diagnostic purposes
- Clinical studies in support of New Drug Application approval by the FDA
- Clinical studies in support of Pre-Market Approval for biomarkers/medical devices by the FDA

Direct your questions about scientific/research issues to:

Gary J. Murray, Ph.D.
Phone: 301-443-9940

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Pharmaceutical Development for Alcoholism Treatment

The topic focuses on applied and, where appropriate, clinical research on pharmacologic agents for use in the treatment or medical management of alcoholism, disorders resulting from alcoholism, the improvement and refinement of drugs currently available for therapeutic purposes, or drugs suitable for use in basic research studies on alcohol addiction. Areas that may be of interest to small businesses include, but are not limited to:

- A. Development of agents to attenuate drinking behavior, e.g., drugs to curb craving
- B. Development of aversive agents such as disulfiram that can attenuate drinking behavior
- C. Development of agents to treat acute alcohol withdrawal
- D. Development of drugs capable of improving or reversing alcohol-induced cognitive impairments
- E. Development of agents to induce sobriety in intoxicated individuals (i.e., amethystic agents)
- F. Development of agents to treat associated psychiatric disorders and/or drug abuse, and to diminish drinking
- G. Development of improved methods of drug delivery for the treatment of alcoholism. The systems developed must be capable of maintaining therapeutic drug levels for extended periods of time to alleviate compliance problems.
- H. Development of drugs for the treatment of alcoholic hepatitis, liver fibrosis, cirrhosis, pancreatitis, cardiomyopathy, or other alcohol-induced tissue damage
- I. Research on the pharmacodynamics and pharmacokinetics of concurrent ethanol and other drug use.

For clinical questions, contact:

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Svetlana Radaeva, Ph.D. (Organ damage)

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Diagnostic Assessment of Alcohol Use Disorders and Comorbidity

Innovative self-report and biochemical approaches to the early identification of alcohol use problems and diagnosis of alcohol use disorders and comorbidity are needed. The research design should include measurements of reliability and validity in appropriate population samples. Areas that may be of interest to small businesses include, but are not limited to:

- A. Development or adaptation of diagnostic instruments measuring alcohol use disorders and related comorbid conditions in general population and treated samples, including youth, the elderly, pregnant women, ethnic minorities, the handicapped, and persons with low-level reading skills).
- B. Development and testing of computer algorithms necessary to derive diagnoses of alcohol use disorders and associated comorbidity.
- C. Development of innovative methods for diagnostic assessment in clinical settings. Development and testing of detailed audio, visual, or printed training modules to accompany diagnostic instruments.

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Treatment of Alcoholism

- A. Development and evaluation of innovative therapeutic approaches across the continuum of alcoholism care.
- B. Development and validation of tools to aid in the clinical management of patients, including selection of appropriate interventions, process evaluation, assessment of outcome, aftercare, and patient tracking, in various treatment settings.

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Alcohol Biosensors and Data Analysis Systems

It is anticipated that innovative and improved alcohol sensors would be useful in a variety of situations including, but not limited to, clinical monitoring, forensics and human or animal research. Specific sensor characteristics would complement their intended use. This applies to characteristics such as sampling frequency, degree of accuracy, data storage capacity and data transmission frequency.

Depending on their intended purpose and use, alcohol sensors may be augmented with additional information such as other physiological measurements or geospatial determinations. Devices need to be compatible with human comfort, and devices to be worn for weeks or months may present particular challenges. Since alcohol readings are likely to be baseline most of the time, these sensing devices generally require ways to monitor contact and readiness to record. Moreover, where necessary, measurement fidelity should be robust to subject's activities including active efforts at tampering.

The mode of data storage will need to conform to power limitations and strategies for data transmission which may require telemetry.

In addition to alcohol monitoring and data transmission this program also includes the opportunity to develop appropriate data analysis systems. Examples include: estimating blood alcohol concentrations, reconstructing patterns of alcohol consumption, and monitoring large numbers of devices to identify significant, but infrequent, events while minimizing false positives.

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Prevention

This area of interest focuses on the development and evaluation of innovative prevention and intervention programs, or specific materials for integration into existing programs, which utilize state-of-the-art

technology and are based on currently accepted clinical and behavioral strategies. Applicants are strongly encouraged to consult with research methodologists and statisticians to ensure that state-of-the-art approaches to design, analysis, and interpretation of studies under this topic are used. Areas that may be of interest to small businesses include, but are not limited to:

- A. Development and evaluation of innovative prevention/intervention programs, or specific materials for integration into existing programs, which utilize state-of-the-art technology and are based on currently accepted clinical and behavioral strategies. Special emphasis should be placed on the needs of high-risk groups, ethnic and minority populations, youth, children of alcoholics, women, the handicapped, and the elderly. Examples of such materials include school-based curricula, interactive videos, computer-based multimedia programs, training manuals for teachers or parents, and community-based programs.
- B. Development and evaluation of educational materials designed to intervene with the elderly around specific age-related risks for alcohol problems. Particular attention should be given to age-related reductions in alcohol tolerance, interactions between alcohol and prescription and over-the-counter medications, possible exacerbation of some medical conditions common among the elderly, potential biomedical and behavioral consequences of excessive alcohol use, and the role of alcohol in falls, fires, burns, pedestrian and traffic injuries, and other unintentional injuries.
- C. Development and evaluation of statistical analysis programs tailored to the design and analysis of alcohol prevention-relevant research. Programs could focus on a variety of areas including: imputation of missing data under varying design assumptions; simulation of distributions of outcomes based on varying mixtures of sample populations; application of chronic or infectious disease models to targeted communities; and models of the potential effect of various policy-based interventions, such as increased taxation or reduction of outlet density by license revocation and control.

Robert C. Freeman, Ph.D.

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Health Services Research on Alcohol-Related Problems

Research projects are sought that will expand knowledge and improve delivery of alcohol treatment and prevention services. The research objectives include, but are not limited to, the effects of organizational structures and financing mechanisms on the availability, accessibility, utilization, delivery, content, quality, outcomes, and costs of alcohol treatment services. Objectives also include studying the effectiveness and cost-effectiveness of alcohol prevention services in reducing the demand for health care services and improving the methodological tools useful for conducting health services research. Areas that may be of interest to small businesses include, but are not limited to:

- A. Development and assessment of protocols to assist in the identification, recruitment, and selection of treatment personnel to enhance the matching of staff to program needs.
- B. Development and assessment of computer software or other protocols to assist in the management of treatment delivery. Software should be useful for assessment, diagnosis, patient placement criteria, monitoring of services received, tracking patient progress, and billing.
- C. Development and assessment of software to assist clinicians in scoring and assessment of score norms for commonly used assessment instruments. These packages should include protocols for guiding client feedback in a clinic or office-based setting.
- D. Development and assessment of software or other protocols to assist treatment programs and service agencies in measuring, assessing, or otherwise documenting clinically relevant performance indicators or improvements in quality of service provision.

- E. Development and assessment of protocols to facilitate the selection, implementation, adoption, and maintenance of evidence-based services consistent with target population need, staffing and program resources, and expected outcomes. These protocols should be flexible enough to work across a variety of settings and modalities.
- F. Development and assessment of software or other protocols to facilitate the incorporation of screening and identification tools into routine usage in primary care, emergency, obstetric, mental health, and other health care settings. Research projects should facilitate both the provisions of brief interventions, medical management, effective referral to specialized alcohol treatment, and follow-up.
- G. Development and assessment of software or other protocols for monitoring service costs of alcohol treatment services including core, ancillary, out-sourced services. These tools should provide a user-friendly system of monitoring costs that could be implemented without additional accounting expertise by the staff at a typical treatment setting. At the same time, such tools should be defensible as measures of the true opportunity costs of providing alcohol treatment services. Such software might be bundled with billing software.

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Fetal Alcohol Spectrum Disorder (FASD) and Alcohol-Related Birth Defects

FASD is the collective term for the broad array of documented adverse effects resulting from in utero alcohol exposure. The most serious of these is fetal alcohol syndrome (FAS), a devastating developmental disorder characterized by craniofacial abnormalities, growth retardation, and nervous system impairments that may include mental retardation. Other diagnostic categories include partial FAS, alcohol-related neurodevelopmental disorder (ARND), and alcohol-related birth defects (ARBD). Children and adults with FASD may exhibit multiple cognitive, behavioral, and emotional deficits that impair daily functioning in many domains. The NIAAA supports research leading to improved diagnosis and assessment of impairment and disability, as well as the development of tools to enhance academic and daily living skills. Areas that may be of interest to small businesses include, but are not limited to:

- A. Development and assessment of diagnostic and/or screening methods that can be used prenatally to identify fetuses affected by ethanol.
- B. Development and validation of biomarkers that can be used to verify prenatal alcohol exposure in neonates.
- C. Development and validation of assessment methods to provide more accurate clinical diagnosis of FASD at all life stages.
- D. Development and testing of skill-building, therapeutic, and education program products that enhance the social, cognitive, adaptive and motor abilities of individuals with FASD.
- E. Development of neurobehavioral tools or instruments to assess responsiveness of individuals with FASD to medications and/or cognitive/behavioral therapies.
- F. Development of accurate measures of the responsiveness of children affected by prenatal exposure to alcohol to stress and predictors of vulnerability to alcohol-drinking or other psychopathology during adolescence and adulthood.
- G. Development and evaluation of educational and training programs designed to enhance the skills of non-professional caregivers in dealing with the problems associated with FAS.
- H. Development and validation of innovative approaches to prevent harmful drinking during pregnancy.

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For prevention research questions, contact:

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Alcohol Use and HIV, HBV, or HCV Infection

Alcohol use, including hazardous drinking, by persons infected with HIV, HBV, and HCV, is quite common in the United States. Alcohol consumption is widely acknowledged as a co-factor in the sexual transmission, susceptibility to infection, and progression of the infectious diseases. However, detailed relationships between alcohol use and viral infections, diseases progression, antiretroviral therapy and adverse outcomes, notably in liver disease progression, are less recognized or understood. Recent research indicates that inflammatory pathways predominate in alcoholic hepatitis whereas adaptive immunity plays a primary role in viral hepatitis, offering multiple targets for novel preventive and therapeutic interventions. Comprehensive studies to improve understanding of the factors underlying alcohol and viral etiologies in liver disease and the impact of antiretroviral drugs on liver disease progression are needed. A better understanding of alcohol's effects on liver disease in patients with HIV/HBV/HCV infection may improve diagnosis and treatment outcomes. NIAAA supports research leading to improved diagnosis and treatment of alcohol-induced disorders in people infected with HIV, HBV, or HCV.

Areas that may be of interest to small businesses include, but are not limited to:

- A. New preventive and therapeutic approaches designed to protect the liver from alcohol and antiretroviral drug-induced liver injury in patients infected with HIV, HBV, or HCV.
- B. Development of therapies aimed at molecular targets that play a role in the development of alcoholic and viral liver diseases.
- C. Develop and evaluate drugs that mitigate the effects of oxidative stress on mitochondrial function thereby preventing liver disease progression.
- D. Development of biomarkers for individuals who are most prone to alcohol-induced damage in those patients infected with HIV, HBV, or HCV.

For HBV/HCV and basic research questions on HIV, contact:

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For clinical or epidemiological questions on HIV, contact:

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Research Tools

The NIAAA supports the development of new or improved tools to enhance the ability to conduct alcohol-related laboratory studies on humans and animals and to more effectively analyze data from large databases. Examples include transgenic animal models, cell lines, new ligands for neuroimaging, and simulators of alcohol impairment. Areas that may be of interest to small businesses include, but are not limited to:

- A. Development of novel animal models, including transgenic animals, possessing specific traits of significance for the study of alcoholism, or for the study of specific pathologic disease states which arise from excessive alcohol consumption.
- B. Development of a hepatocyte cell line capable of maintaining viability and metabolic functions in culture systems for an indefinite period.
- C. Development of new methods of ethanol administration to animals that produce precise dose control or that closely mimic types of alcohol exposure occurring in humans, including, but not limited to, binge drinking, acute consumption, moderate consumption and chronic consumption.
- D. Development of specialized cell culture chambers to provide controlled administration of ethanol to *in vitro* cell systems.
- E. Development of ligands which will enhance the potential usefulness of PET and SPECT imaging technologies for the study of the etiology of alcoholism and related brain pathology.
- F. Development of genetic, epigenetic, genomic, proteomic, metabolomic, lipidomic, glycomic or other systems-wide methods for assessment, prognosis, diagnosis or treatment of alcohol-induced disorders.
- G. Development of computational, statistical or bioinformatics tools to organize and manage high throughput data obtained by genomic, functional genomic or other 'omic strategies.
- H. Development of databases, methods for integration of databases, or data analysis systems for alcohol research.

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Development of Biomolecular Signatures of Alcohol Exposure and Alcohol-induced Tissue Injury

Acute and chronic alcohol consumption leads to health-related complications and ultimately to significant societal costs. Quantitative and qualitative markers of high-risk drinking behavior and alcohol-induced tissue damage would greatly improve medical efforts to recognize and treat alcohol-related disorders. Traditional biomarkers currently in clinical use lack specificity, sensitivity, and accuracy, and fail to provide long-term information. Biomarkers of sufficient reliability, sensitivity and specificity are likely to be comprised of a panel of physiological parameters, rather than a single molecular entity. Thus, NIAAA seeks to support the discovery and development of pattern-based molecular fingerprints or signatures of alcohol consumption and of alcohol-induced tissue injury. High throughput approaches using genomics, epigenomics, transcriptomics, proteomics, metabolomics, lipomics, or glycomics are encouraged. Biomarker signatures may be composed of multiple genes, RNAs, microRNAs, proteins, or metabolites, or combinations thereof. Furthermore, alterations in lipid, lipoprotein, or glycoprotein profiles may reflect the metabolic effects of alcohol exposure and may be considered as potentially predictive. Biomarker signatures that address multiple aspects of alcohol consumption and alcohol damage are needed. These include, but are not limited to:

- A. Biomarkers of long-term alcohol consumption. A biomarker panel reflecting the cumulative intake of alcohol over a period of months or more would be of great diagnostic use, both in terms of recognizing problem drinking and in terms of the potential for organ damage.
- B. Biomarkers that distinguish between binge, acute, moderate and chronic drinking. Each of these modes of alcohol intake has different physiological effects. The ability to distinguish dose and timing of drinking would enhance clinicians' ability to design appropriate treatment and intervention protocols.
- C. Biomarkers of compliance after withdrawal. Biomarker signatures in this class would be comprised of metabolic products that decrease rapidly upon abstinence, in contrast to the characteristics of biomarkers that reflect cumulative alcohol. The ability to detect relapse accurately will support successful behavioral interventions.
- D. Biomarker signatures of alcohol-induced organ damage. The damage due to alcohol consumption is likely to be organ-specific, with signatures reflecting alcohol-induced damage likely to be different for heart damage, liver damage, encephalopathy, a dysregulated immune system, or other alcohol target.
- E. Biomarker signatures of familial risk factors for alcoholism. Early identification of subjects predisposed to alcoholism will allow for early intervention, and allow subjects to make informed decisions.

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Clinical Testing of Biochemical Markers

The development of effective biochemical markers represents a powerful means for early diagnosis and treatment of alcohol dependent/abuse patients and for the identification of individuals who have a predisposition for alcoholism. There are two different types of biochemical markers: trait markers and state markers.

Trait biomarkers have the ability to detect inborn characteristics of individuals who are vulnerable for alcoholism. This type of marker would be invaluable for screening of high-risk individuals (e.g., children of alcoholics) and targeting them with preventive or early treatment interventions. In addition, trait markers might assist practitioners in identifying subpopulations of alcoholics who may need different treatment strategies. An ideal trait marker should have several features. First, it should display validity in detecting people susceptible to alcoholism, particularly before the onset of alcoholism or during periods of stable abstinence. Second, it should be easily and reliably measured. Third, it should be specific for alcoholism only and not affected by other medical or psychiatric disorders or drugs. Since alcoholism is a complex disease, it is likely that more than one type of gene and protein exist as trait marker.

State markers or markers of alcohol consumption serve several important purposes. First, they can assist physicians in diagnosing individuals with chronic drinking problems, particularly patients who deny excessive drinking. Moreover, they may also identify individuals in early stages of heavy drinking, thus avoiding the long-term medical, psychological, and social consequences of chronic alcoholism. Second, state biomarkers can aid in the diagnosis and treatment of other diseases (liver diseases, pancreatitis, and cardiovascular diseases) that were, at least, caused by excessive drinking. Third, they are useful in alcohol treatment and prevention programs. Since the goal of many of programs is abstinence, monitoring relapse is important in gauging success. Last, state biomarkers are important in clinical alcohol trials. Although self-reports have become more sophisticated and valid (e.g., Timeline Followback), they still rely on accurate reporting. These new and reliable biomarkers could then be used to confirm the self-report. Several biomarkers with certain limitations are currently in use including carbohydrate-deficient transferrin (CDT), gamma-glutamyl transferase (GGT), aspartate aminotransferase (AST), alanine aminotransferase

(ALT), and mean corpuscular volume (MCV). New state markers need to be developed that incorporate the following attributes: validity, reliability, stability, cost, practicability, acceptability, and transportability.

Areas that may be of interest to small businesses include, but are not limited to:

- A. Develop and evaluate clinically alcohol-sensitive biomarkers to identify individuals who are predisposed to alcoholism; determine relapse; measure levels of drinking; and determine alcohol-induced tissue damage.
- B. Identify genes, and proteins that are expressed during the development of alcohol dependence for biomarker development.
- C. Develop methodologies for high throughput identification of alcohol metabolites and other signaling molecules that are expressed during alcohol intake.
- D. Use knowledge of genetic and molecular mechanisms underlying alcohol-induced organ damage (including alcohol-related liver, pancreas, heart disease and FAS) to develop new biomarkers of tissue and cell damage.
- E. Evaluate clinically innovative alcohol-sensitive biomarkers (trait, relapse, organ damage) for sensitivity and specificity.

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Stem Cell Research for Alcohol-induced Disorders

Stem cells are master cells in the body and they have the remarkable potential to develop into many different cell types. Stem cells may become a renewable source of replacement cells to treat alcohol related diseases. They can also be used to study disease processes, and to develop new and more effective drugs.

Recent research progress on stem cells has offered great opportunities to study conditions and diseases related to alcohol abuse and alcoholism. Stem cells can come from embryos or adult tissues. They are generally categorized into 1) Embryonic stem cells; 2) Induced pluripotent stem cells (iPS cells); and 3) Adult stem cells. The NIAAA supports SBIR/STTR research using any of these 3 types of stem cell, which can lead to improved understanding of alcohol related diseases and conditions, and better treatment.

Areas that may be of interest to small businesses include, but are not limited to:

- A. Generate and disseminate induced pluripotent stem cells (iPS) from mature human cells to resemble diverse individual variations regarding alcohol metabolism. Use these genetic variant models to study alcohol dependence and pharmacotherapy development. Examples of these genetic variations include Alcohol Dehydrogenase (ADH), Aldehyde Dehydrogenase (ALDH), cytochrome P450 isozyme CYP2E1, and Glutathione S transferase (GST).
- B. Generate and disseminate disease-specific iPS cell lines for studies on the biology and signaling pathways that contribute to the alcohol-related disease pathology.
- C. Study the potential of using patient-specific iPS cells for cell replacement therapies to treat alcohol-caused tissue damages.

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Real-time Detection of Neurochemical Changes in Response to Alcohol Drinking

Many pharmacological mechanisms of ethanol action in the brain are mediated by time-dependent neurochemical events in multiple brain regions. Despite great progress in identifying ethanol's neurochemical actions, we do not fully know how neurochemicals change in real time following ethanol administration and drinking (acute and chronic). Multidimensional measurement of neurochemical change (i.e., concentration, time, region) are needed to reveal kinetics underlying alcohol effects to guide future medication development and promote mechanistic understanding of alcohol drinking.

With this SBIR/STTR grant solicitation, NIAAA seeks development of biosensors enabling monitoring of regional neurochemical changes in the brains of rats and/or mice in real time as they drink alcohol. Recent studies report the plausibility of using microsensors coupled with wireless detection methods to instantaneously monitor multiple neurochemical changes in animals. NIAAA seeks development of microsensors with sufficient resolution to provide neuroanatomical regional specificity. In addition to brain ethanol concentration, neurochemicals of interest include, but are not limited to, glutamate, dopamine, GABA, acetylcholine, and signaling molecules. Work under this solicitation should be directed toward the development of commercial strategies for the real-time measurement of extracellular neurochemical and brain ethanol concentrations in behaving animals.

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Develop Network Pharmacology Strategy for Preclinical Medication Development

The frequent failure of using highly selective drugs for disease treatment has challenged the concept of "one gene, one drug and one disease" and led to the emergence of a new paradigm, network pharmacology, as a drug development and treatment strategy. This strategy combines the knowledge of biological networks with multiple drug targets to simultaneously regulate multiple pathways perturbed by disease conditions. Given the multi-target nature of alcohol action, alcoholism arises from brain network perturbation. The network pharmacology/combined pharmacological approach, either using drug combinations or multi-target drugs, may serve as an effective strategy for the treatment of alcohol-induced brain dysfunction and behavior disorders.

NIAAA seeks preclinical development of combined pharmacological approaches to synergistically regulate multiple drug targets for alcoholism. Areas that may be of interest to small businesses include, but are not limited to:

- Objective 1: Develop and validate new target combinations using cellular and animal models.
- Objective 2: Prioritize multi-drug targets and identify the effective drug combinations or multi-target drugs for the medication development.
- Objective 3: Use high-throughput screening of compound libraries to identify multi-target drugs.
- Objective 4: Encourage adaption of low throughput assays to high throughput screening, development of lead compounds, and identification of drug candidate(s) with proper pharmaceutical properties for medication development.

Changhai Cui, Ph.D.
301-443-1678
Email: Changhai.Cui@nih.gov

Other Research Topic(s) Within the Mission of the Institute

For additional information on research topics, contact:

Gary J. Murray, Ph.D.
National Institute on Alcohol Abuse and Alcoholism
5635 Fishers Lane, Room 2037
Bethesda, MD 20892-9304
For Federal Express delivery, use:
Rockville, MD 20852-1705
Phone: 301-443-9940
Email: Gary.Murray@nih.gov

For administrative and business management questions, contact:

Ms. Judy Fox
Grants Management Officer
National Institute on Alcohol Abuse and Alcoholism
Phone: 301-443-4704, Fax: 301-443-3891
Email: Judy.Fox@nih.gov

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES (NIAID)

The NIAID's Division of AIDS, Division of Allergy, Immunology, and Transplantation, and Division of Microbiology and Infectious Diseases fund SBIR/STTR grants on topics related to their mission and activities as described below. Questions on specific research areas may be addressed to the NIAID Program Officials listed below. General questions on the NIAID SBIR and STTR programs and on administrative and business management may be addressed to contacts listed for the NIAID section. When possible, *applicants are encouraged to use email* for communication.

For information about NIAID's Small Business Programs, please visit
<http://www.niaid.nih.gov/researchfunding/sb/pages/default.aspx>.

Limited Amount of Award (Total not Annual)

For budgetary or programmatic reasons, NIAID may decrease the length of an award or the amount of an award from that approved by peer review. Applicants considering requesting a Phase I grant greater than \$300,000 total cost or a Phase II grant greater than \$2 million total cost are strongly encouraged to contact Gregory Milman (below) before submitting an application.

Phase IIB SBIR Competing Renewal Awards

The NIAID will accept Phase IIB SBIR Competing Renewal grant applications to continue the process of developing products that require approval of a regulatory agency (e.g., FDA). Projects that are particularly encouraged include those in the NIAID Small Business High Priority Areas of Interest (<http://www.niaid.nih.gov/researchfunding/sb/pages/sbirareas.aspx>). NIAID will not accept Phase IIB STTR Competing Renewal applications.

NIAID will accept Phase IIB SBIR Competing Renewal applications for a project period of up to three years and a budget not to exceed a total cost of \$1 million per year (including direct cost, F&A, and fee/profit) provided the time period and amount are well justified.

The total amount of all consultant costs and contractual costs normally may not exceed 50% of the total costs requested for initial SBIR Phase II applications. NIAID SBIR Phase IIB Competing Renewal grant

applications may exceed this guideline, however, when well justified and when those costs are necessary to support preclinical studies and related expenses. Examples of well founded reasons for exceeding this guideline include, but are not limited to, subcontracts for safety, toxicity, or efficacy testing in animals, and subcontracts to assure compliance with Good Manufacturing Practices expectations of the FDA.

Human clinical trials may not be a component of proposed SBIR or STTR research. See Notice of NIAID Policy on investigator initiated clinical trials at <http://grants.nih.gov/grants/guide/notice-files/NOT-AI-10-024.html>. Small business applicants are encouraged to contact Gregory Milman (below) to discuss NIAID funding for human clinical trials.

NIAID does NOT request a letter of intent for Phase IIB Competing Renewal Applications. However, prior to submission, applicants are strongly encouraged to contact:

Gregory Milman, Ph.D.
Division of Extramural Activities
National Institute of Allergy and Infectious Diseases
Room 2130, MSC-7610
6700-B Rockledge Drive
Bethesda, MD 20892-7610 (US Mail)
Rockville, MD 20817-7610 (Delivery Services)
Telephone 301-496-8666
Fax: 301-402-0369
Email: gm16s@nih.gov

Division of AIDS

The Division of AIDS (DAIDS) supports research on the pathogenesis, natural history, and transmission of HIV and HIV disease, and promotes progress in its detection, treatment, and prevention.

Director: Dr. Carl Dieffenbach
301-496-0545
Email: cd17u@nih.gov

BASIC SCIENCES PROGRAM

Supports basic and applied research on the causes, diagnosis, treatment and prevention of HIV and AIDS.

Director: Dr. Susan Plaeger
301-402-9444
Email: splaeger@niaid.nih.gov

- A. **Epidemiology Branch.** Population-based research and modeling studies of HIV transmission and associated biological and behavioral factors. Also, the treated and natural history of HIV, including research on immunology, virology, therapy and other issues surrounding care, and other co-morbidities, their interactions and impact on clinical outcome.

Contact: Joana Roe
301-435-3759
Email: jr108r@nih.gov

- B. **Basic Research Branch.** Identification and characterization of potential targets for discovery or design of novel strategies to impact HIV transmission, virus-host interactions, host restriction factors, chronic immune activation, and HIV latency/persistence. Innovative approaches for monitoring or studying HIV infection, immunopathogenesis, and viral reservoirs that persist despite antiretroviral

therapy. Development of assays and technologies involving nanotechnology and single-cell analysis is of particular interest.

Contact: Dr. Karl Salzwedel
301-496-5332
Email: salzwedelkd@niaid.nih.gov

- C. **Targeted Interventions Branch.** Research areas: (1) targeted therapeutics emphasizing under-explored viral and cellular targets; (2) innovative therapeutic strategies including immune-based and gene-based therapies and therapeutic vaccines; (3) translational research for effective therapeutics; (4) animal models for evaluating new therapeutic entities, regimens, and strategies; and (5) therapeutic approaches using nanotechnology.

Contact: Dr. Roger Miller
301-496-6430
Email: rm42i@nih.gov

VACCINE RESEARCH PROGRAM

Supports the development of vaccines to prevent AIDS.

Acting Director: Dr. Alan Fix
301-594-9953
Email: affix@niaid.nih.gov

- A. **Vaccine Clinical Research and Development Branch.** Research areas: (1) coordination of phase I, II, and III domestic and international clinical trials of candidate AIDS vaccines; (2) coordination of the characterization of immune responses in HIV-infected and uninfected immunized volunteers, using micro and macro assays; and (3) coordination of studies to identify, validate, and standardize immunologic and virologic markers for monitoring response of participants in vaccine clinical trials.

Contact: Dr. Jim Lane
301-451-2758
Email: laneji@mail.nih.gov

- B. **Preclinical Research and Development Branch.** Support of applied preclinical development of candidate AIDS vaccines, delivery methods and novel vaccine vectors, and adjuvants for the prevention of AIDS; promotion and evaluation of safety and efficacy of the prevention modalities, especially novel vaccine concepts identified in preclinical models including trials in non-human primates; genetic and immunologic variation; and mucosal immunity in SIV, HIV, and SHIV models.

Contact: Dr. Yen Li
301-496-3816
Email: yli@niaid.nih.gov

THERAPEUTICS RESEARCH PROGRAM

Develops and oversees research and development of therapies for HIV disease, including complications, co-infections, co-morbidities and cancers, in adults, infants, children, and adolescents.

Acting Director: Dr. Carla Pettinelli
301-402-5582
Email: pettinelli@niaid.nih.gov

- A. **Drug Development and Clinical Sciences Branch.** Discovery and preclinical development of experimental therapies for HIV, TB and other infectious diseases; maintenance of a database of potential anti-HIV and anti-opportunistic infection compounds; immunologic, virologic, and pharmacologic research related to the design and conduct of clinical trials.

Chief: Dr. Mike Ussery
301-402-0134
Email: mussery@niaid.nih.gov

- B. **HIV Research Branch.** Clinical research of strategies to treat adult primary HIV infection and complications; strategies to augment HIV immune responses and general host immunity.

Contact: Tia Morton
301-435-3763
Email: frazierti@niaid.nih.gov

- C. **Complications & Co-Infections Research Branch.** Preclinical and clinical research to develop new or improved therapies for the treatment and prophylaxis of Pneumocystis carinii pneumonia, Mycobacterium avium disease, and cryptococcosis. Evaluation of diagnostics of or agents for treatment or prevention of hepatitis B or hepatitis C secondary to HIV infection in adults.

Contact: Dr. Chris Lambros
301-435-3769
Email: clambros@niaid.nih.gov

- D. **International Maternal, Adolescent and Pediatric Medicine Branch.** HIV therapies in children and adolescents. Strategies to reduce transmission from mother to infant or fetus.

Chief: Dr. Ed Handelsman
301-402-3221
Email: handelsmane@niaid.nih.gov

- E. **Tuberculosis Clinical Research Branch.** Clinical research for tuberculosis, with and without HIV co-infection, to facilitate the development of biomarkers/diagnostics, therapies, and prevention/vaccines.

Contact: Dr. Peter Kim
301-451-2761
Email: kimp2@niaid.nih.gov

PREVENTION SCIENCE PROGRAM

Conduct basic research on mechanisms of HIV transmission supportive of new biomedical strategies for interrupting transmission. Conduct of domestic and international phase I, II, and III clinical trials to evaluate HIV/AIDS prevention strategies, including microbicides, chemoprophylactic agents, and other biomedical and behavioral risk reduction interventions.

Acting Director: Sheryl Zwierski, MSN, CRNP
301-402-4032
Email: szwerski@niaid.nih.gov

- A. **Preclinical Microbicides and Prevention Research Branch.** Manage and oversee the preclinical pipeline for non-vaccine biomedical prevention products including topical microbicide and pre-exposure prophylaxis (PrEP) candidates. Integrate and support iterative approaches of existing and emerging technologies into a translational pipeline to select and advance the most promising candidates to clinical evaluation.

Chief: Dr. Jim Turpin
301-451-2732
Email: jturpin@niaid.nih.gov

- B. **Clinical Microbicide Research Branch.** Foster and facilitate the clinical development of promising microbicides to prevent HIV infection with the ultimate goal to advance safe, effective and acceptable microbicide products toward licensure.

Chief: Dr. Roberta Black
301-496-8199
Email: rblack@niaid.nih.gov

- C. **Clinical Prevention Research Branch.** Foster the development of safe and effective non- vaccine biomedical and integrated HIV prevention interventions to reduce the number of new HIV infections in adults and adolescents. Support the development of HIV incidence assays, biomarkers of adherence, and mathematical modeling.

Chief: Dr. David Burns
301-435-8896
Email: burnsda@niaid.nih.gov

Division of Allergy, Immunology, and Transplantation

The Division of Allergy, Immunology, and Transplantation (DAIT) supports studies of the immune system in health and the cause, pathogenesis, diagnosis, prevention, and treatment of disease caused by immune dysfunction.

Director: Daniel Rotrosen, M.D.
301-496-1886
Email: drotrosen@niaid.nih.gov

- A. **Asthma, Allergy, and Inflammation Branch.** Asthma, atopic dermatitis, hypersensitivity reactions, rhinitis, sepsis, sinusitis, urticaria, basic studies of asthma and allergy mechanisms, new therapies to prevent or treat asthma and allergic diseases, food allergies, epidemiology and prevention, phagocyte biology, eosinophilic gastroenteritis, and mechanisms of host defense. Methodologies to design, manage, and analyze clinical and epidemiologic research of the etiology, prevention, and treatment of asthma, allergy, and inflammatory diseases.

Chief: Dr. Matthew Fenton
301-451-0144
Email: fentonm@niaid.nih.gov

- B. **Basic Immunology Branch.** Origin, maturation, and interactions of immune cells, immune cell receptors, ligands, cytokine biology, molecular basis of activation, antigen recognition, immune tolerance, immune response regulation, hematopoiesis and stem cell biology, enhancement of vaccine effectiveness in neonates and adults, and basic immunology of vaccines and immunotherapeutics as medical countermeasures for biodefense.

Chief: Dr. Helen Quill
301-496-7551, Fax: 301-480-2381
Email: hquill@niaid.nih.gov

- C. **Clinical Immunology Branch.** Preclinical and clinical research to develop and improve therapies for the treatment of autoimmune diseases, primary immune deficiencies (not HIV), basic research of disease mechanisms, and biomarkers, immunotherapy of disease processes, disorders mediated by lymphocyte products, and mucosal immunity.

Chief: Dr. James McNamara
301-451-3121, Fax: 301-480-1450
Email: jmcnamara@niaid.nih.gov

- D. **Transplantation Immunobiology Branch.** Acute and chronic graft rejection, allogeneic and xenogeneic transplantation, development of immunomodulatory agents to prevent and treat graft rejection, genomics of the alloimmune response, hematopoietic stem cell transplantation, major histocompatibility complex, minor histocompatibility antigens, infectious and malignant complications of immunosuppression in transplantation, and technologies for MHC typing.

Chief: Dr. Nancy Bridges
301-496-5598
Email: nbridges@niaid.nih.gov

- E. **Radiation Countermeasures Program.** Mitigators and therapeutics for acute radiation syndrome or the delayed effects of acute radiation exposure; radionuclide-specific therapies, including chelating agents, blocking agents, and other novel decorporation agents; improved methods of radiation biodosimetry and bioassay for radionuclide contamination; biomarkers of organ-specific radiation injury; therapeutics for radiation combined injury; therapeutics for radiation-induced immunosenescence, formulations for pediatric administration.

Chief: Dr. Bert Maidment
301-594-0641
Email: maidmentb@niaid.nih.gov

Division of Microbiology and Infectious Diseases

The Division of Microbiology and Infectious Diseases (DMID) supports research to better understand, treat, and ultimately prevent infectious diseases caused by virtually all infectious agents, except HIV. DMID supports a broad spectrum of research from basic molecular structure, microbial physiology and pathogenesis, to the development of new and improved vaccines and therapeutics. DMID also supports medical diagnostics research, which is defined as research to improve the quality of patient assessment and care that would result in the implementation of appropriate therapeutic or preventive measures. DMID does not support research directed at decontamination or the development of environmentally oriented detectors, whose primary purpose is the identification of specific agents in the environment. Note that some of the organisms and toxins listed below are considered NIAID priority pathogens or toxins for biodefense and emerging infectious disease research.

Director: Dr. Carole Heilman
301-496-1884
Email: ch25v@nih.gov

- A. **Bacteriology and Mycology Branch.** The branch oversees research on medical mycology, hospital infections (including *Acinetobacter*, *Klebsiella*, *Serratia*, *Legionella*, *Pseudomonas*, *Aeromonas*, *Enterobacter*, *Proteus*, non-enteric *E. coli*, actinomycetes and others), staphylococci, enterococci, bacterial zoonoses (plague, anthrax, tularemia, glanders, melioidosis, Lyme disease, rickettsial diseases, anaplasmosis, ehrlichiosis and Q fever), and leptospirosis. Research is encouraged in the following general areas: (1) product vaccines, adjuvants, therapeutics and diagnostics (including target identification and characterization, device or apparatus development, novel delivery, and preclinical evaluation); (2) products to combat antibacterial and antifungal drug resistance; (3) applied proteomics and genomics; (4) host-pathogen interactions, including pathogenesis and host response; (5) genetics, molecular, and cell biology; and (6) microbial structure and function.

Research in the following areas is of particular interest to the branch, but research on all of the above is welcome:

- Vaccines, therapeutics, and medical diagnostics for hospital infections
- Adjunctive therapies to combat antimicrobial resistance
- Diagnostics for aspergillosis
- Novel approaches for the diagnosis of Lyme disease

Contact: Dr. Alec Ritchie

301-402-8643, Fax: 301-402-2508

Email: aritchie@niaid.nih.gov

- B. **Enteric and Hepatic Diseases Branch.** Special emphasis areas include vaccines against hepatitis C virus; antimicrobials and antivirals that focus on novel targets such as host-pathogen interactions to combat the development of resistance; vaccines and therapies for botulinum neurotoxins, especially therapies that target toxins once they enter cells; therapies and diagnostics for *Clostridium difficile* that include recurrent disease issues; development of a simple, rapid point-of-care diagnostic tool for the simultaneous identification of multiple diarrheal pathogens that includes their antibiotic resistance profiles; pediatric vaccines to prevent the major worldwide causes of diarrhea; more stable vaccines and improved formulation methods; and novel therapeutics for chronic hepatitis B and C.

Research areas of the Branch include the following organisms and diseases: astrovirus, *Bacteroides spp.*, *Campylobacter spp.*, enteric *Clostridia spp.* including botulinum neurotoxins, commensals and normal flora, pathogenic *Escherichia coli*, gastroduodenal disease, gastroenteritis, *Helicobacter spp.*, *Listeria spp.*, Noroviruses including Norwalk, ricin toxin, rotaviruses, *Salmonella* serovars, *Shigella spp.*, Staphylococcus enterotoxin B, *Vibrio spp.* enteric *Yersinia spp.*, hepatitis viruses A, B, C, D, and E, as well as cholera, diarrhea, enterotoxins, gastroenteritis, gastroduodenal disease and ulcers, and Guillain-Barre syndrome.

Program Contact: Dr. Marian Wachtel

301-451-3754, Fax: 301-402-1456

Email: wachtelm@niaid.nih.gov

- C. **Parasitology and International Programs Branch.** Research areas: (1) protozoan infections, including amebiasis, cryptosporidiosis, cyclosporiasis, giardiasis, leishmaniasis, malaria, trypanosomiasis, toxoplasmosis; helminth infections, including cysticercosis, echinococcosis, lymphatic filariasis, schistosomiasis, onchocerciasis, others (e.g., roundworms, tapeworms, and flukes); invertebrate vectors/ectoparasites, black flies, sandflies, tsetse flies, mosquitoes, ticks, snails, mites; (2) parasite biology (genetics, genomics, physiology, molecular biology, and biochemistry); (3) protective immunity, immunopathogenesis, evasion of host responses; (4) clinical, epidemiologic, and natural history studies of parasitic diseases; (5) research and development of vaccines, drugs, immunotherapeutics, and medical diagnostics, and (6) vector biology and management; mechanisms of pathogen transmission.

Chief: Dr. Lee Hall

301-496-2544, Fax: 301-402-0659

Email: lhall@niaid.nih.gov

- D. **Respiratory Diseases Branch.** Research areas: (1) viral respiratory diseases caused by human coronaviruses (SARS), influenza viruses, respiratory syncytial virus and other related paramyxoviruses; (2) **mycobacterial diseases**, including tuberculosis, leprosy, Buruli ulcer and non-tuberculous mycobacterial diseases; (3) **other bacterial respiratory diseases** including acute otitis media, community acquired pneumonia, acute exacerbations of chronic obstructive pulmonary disease, diphtheria, pertussis, acute rhinosinusitis, streptococcal (group A, B) disease; and (4) **mixed viral/bacterial respiratory infections.**

Special emphasis areas: maternal immunization, development of new or improved antimicrobials and antivirals, including immunotherapeutics, new or improved vaccines (with and without adjuvants), improved delivery systems for drugs/vaccines, biomarkers, rapid multiplex diagnostic tests, including low cost point-of-care, or other tools to detect infection prior to active disease and identify drug resistance. There is particular need for preventive and treatment countermeasures for influenza including universal vaccine platforms and broad-spectrum antivirals.

Contact: Dr. Gail Jacobs

301-496-5305, Fax: 301-496-8030

Email: ggjacobs@niaid.nih.gov

- E. **Sexually Transmitted Infections Branch.** Areas of emphasis include the development of medical diagnostics including better and more rapid multiplex point of care tests and other screening or novel delivery systems for diagnostic tools, topical microbicides, vaccines and drugs for sexually transmitted infections (STIs) and other reproductive tract syndromes, such as bacterial vaginosis; molecular immunology; vaginal ecology and immunology; epidemiologic and behavioral research including strategies to reduce transmission of STIs; genomics and proteomics of sexually transmitted pathogens; adolescents and STIs; STIs and medically underserved populations and minority groups; STIs and infertility and adverse outcomes of pregnancy; role of STIs in HIV transmission; role of HIV in altering the natural history of STIs; and other sequelae of STIs.

Contact: Elizabeth Rogers
301-451-3742, Fax: 301-480-3617
Email: erogers@niaid.nih.gov

- F. **Virology Branch.** Areas of emphasis for SBIR/STTR applications include: 1) vaccine development; 2) viral vectors; 3) structure and function of viruses and viral proteins as targets for therapeutic interventions or diagnostics; 4) the development and validations of assays for disease diagnosis and to measure response to therapy; 5) the development and preclinical testing of immunotherapeutic and antiviral drugs for acute and chronic viral illnesses; 6) approaches to identify antiviral targets and agents; 7) chemical design and synthesis of novel antiviral agents; 8) preclinical antiviral evaluations including *in vitro* screening and prophylactic or therapeutic antiviral evaluations of human viral infections in animal models; 9) the development of rapid medical diagnostic systems.

The Virology Branch focuses on the following: acute viral infections (including Nipah and Hendra viruses), arthropod-borne and rodent-borne viral diseases (including Dengue, West Nile, Japanese encephalitis, Chikungunya, yellow fever, hantavirus, etc.), viral hemorrhagic fevers (Ebola, Lassa fever, etc.), measles, polio, coxsackie virus, enterovirus 71 and other enteroviruses, poxviruses, rabies, and rubella. The Virology Branch also focuses on the following persistent viral diseases and viruses: adenoviruses, BK virus, bornaviruses, coronaviruses, herpesviruses, human T-lymphotrophic virus, JC virus, human papillomaviruses, parvoviruses, emerging human polyomaviruses, and prion diseases. Applications targeting the development of therapies, immunotherapies, vaccines and diagnostics for any of these infections are sought. The Virology Branch does not support applications covering environmental detection and decontamination.

Contact: Dr. Ramya Natarajan
301-594-1586, Fax: 301-402-0659
Email: ramya.natarajan@nih.gov

Other Research Topic(s) Within the Mission of the Institute

For additional information on research topics, contact:

Dr. Gregory Milman
National Institute of Allergy and Infectious Diseases
301-496-8666, Fax: 301-402-0369
Email: gmilman@niaid.nih.gov

For administrative and business management questions, contact:

Mr. Michael Wright
Grants Management Specialist
National Institute of Allergy and Infectious Diseases
301-451-2688, Fax: 301-493-0597
Email: mawright@mail.nih.gov

NATIONAL INSTITUTE OF ARTHRITIS AND MUSCULOSKELETAL AND SKIN DISEASES (NIAMS)

The mission of the National Institute of Arthritis and Musculoskeletal and Skin Diseases is to support research into the causes, treatment, and prevention of arthritis and musculoskeletal and skin diseases, the training of basic and clinical scientists to carry out this research, and the dissemination of information on research progress in these diseases.

For additional information about areas of interest to the NIAMS, please visit NIAMS Long Range Plan at http://www.niams.nih.gov/About_Us/Mission_and_Purpose/long_range.asp.

Arthritis and Musculoskeletal and Skin Diseases

- A. ***Division of Skin and Rheumatic Diseases.*** This division promotes and supports: basic and clinical studies of the skin in normal and disease states; and research leading to prevention, diagnosis and cure of rheumatic and related diseases. In the area of Skin Diseases, the division has a wide range of skin diseases under study with NIAMS support, to include keratinizing disorders such as psoriasis and ichthyosis, atopic dermatitis and other chronic inflammatory skin disorders, the vesiculobullous diseases such as epidermolysis bullosa and pemphigus, acne, and vitiligo. In the area of Rheumatic Diseases, the division supports basic, epidemiologic, and clinical research on etiology, pathogenesis, course, interventions, and outcomes in rheumatic and related diseases.

This is not an inclusive list of all research topics covered by the Division of Skin and Rheumatic Diseases. To learn more, please visit the Division page at http://www.niams.nih.gov/Funding/Funding_Opportunities/Supported_Scientific_Areas/Skin_Rheumatic_Diseases/default.asp.

- B. ***Division of Musculoskeletal Diseases.*** The musculoskeletal system is comprised of the skeleton, which provides mechanical support and determines shape; the muscles, which power movement; and connective tissues such as tendon and ligament, which hold the other components together. The cartilage surfaces of joints and the intervertebral discs of the spine allow for movement and flexibility.

The Division of Musculoskeletal Diseases of the NIAMS supports research aimed at improving the diagnosis, treatment, and prevention of diseases and injuries of the musculoskeletal system and its component tissues. Key public health problems addressed by this research include osteoporosis, osteoarthritis, and muscular dystrophy. Research is conducted at every level, from fundamental biology to clinical intervention.

This is not an inclusive list of all research topics covered by the Division of Musculoskeletal Diseases. To learn more, please visit the Division page at http://www.niams.nih.gov/Funding/Funding_Opportunities/Supported_Scientific_Areas/Musculoskeletal_Diseases/default.asp.

For general SBIR/STTR program information, contact:

Dr. Xibin Wang, NIAMS SBIR/STTR Coordinator
301-451-3884, Fax: 301-480-1284
Email: wangx1@mail.nih.gov

For administrative and business management questions, contact:

Ms. Sheila Simmons
301-594-9812, Fax: 301-480-5450
Email: simmonss@mail.nih.gov

Mr. Erik (Timothy) Edgerton

301-594-3968, Fax: 301-480-5450

Email: edgertont@mail.nih.gov

NATIONAL INSTITUTE OF BIOMEDICAL IMAGING AND BIOENGINEERING (NIBIB)

The mission of the National Institute of Biomedical Imaging and Bioengineering (NIBIB) is to improve health by leading the development and accelerating the application of biomedical technologies. The Institute is committed to integrating the physical and engineering sciences with the life sciences to advance basic research and medical care. This is achieved through: research and development of new biomedical imaging and bioengineering techniques and devices to fundamentally improve the detection, treatment, and prevention of disease; enhancing existing imaging and bioengineering modalities; supporting related research in the physical and mathematical sciences; encouraging research and development in multidisciplinary areas; supporting studies to assess the effectiveness and outcomes of new biologics, materials, processes, devices, and procedures; developing technologies for early disease detection and assessment of health status; and developing advanced imaging and engineering techniques for conducting biomedical research at multiple scales. More specifically, the mission of the NIBIB includes the following research areas:

- A. **Biomaterials.** Development of new or novel biomaterials that can be used for a broad spectrum of biomedical applications such as implantable devices; drug and gene delivery; tissue engineering; imaging agents; and biosensors and actuators. Research that is supported includes the design, synthesis, characterization, processing and manufacturing of these materials as well as the design and development of devices constructed of these materials and their clinical performance.
- B. **Biomechanics and Rehabilitation Engineering.** Research on biomechanics which can be applied to a broad range of applications including implants, prosthetics, clinical gait and posture biomechanics, traumatic injury, repair processes, rehabilitation, sports and exercise, as well as technology development in other NIBIB interest areas applied towards biomechanics. Rehabilitation engineering research that is supported includes theoretical models and algorithms for understanding neural, motor, and robotic control strategies; quantitative analysis algorithms for predicting therapeutic outcomes; and early stage development of neuroprosthesis technology, virtual rehabilitation, and robotics rehabilitation.
- C. **Biomedical Informatics.** Development of new technologies to collect, store, retrieve, and integrate quantitative data; large-scale data-driven knowledge base and database methods that support data mining, statistical analysis, systems biology and modeling efforts; and improvement of computer science methods to protect confidentiality of patient data.
- D. **Drug and Gene Delivery Systems and Devices.** Development of new and improved technologies for the controlled and targeted release of therapeutic agents. Areas of emphasis include: the development of new delivery vehicles such as nanoparticles and micellar systems; energy-assisted delivery using ultrasound, electroporation, etc.; and the integration of biosensing with controlled dosage delivery using BioMEMS and other emerging technologies.
- E. **Image-Guided Interventions.** Research on use of images for guidance, navigation and orientation in minimally invasive procedures to reach specified targets. Examples include image-guided interventions for minimally invasive therapies such as surgery and radiation treatment, for biopsies, and for the delivery of drugs, genes and therapeutic devices.
- F. **Image Processing, Visual Perception, and Display.** Study, invention, and implementation of structures and algorithms to improve communication, understanding, and management of information related to biomedical images. Research that is supported includes software and hardware for image reconstruction, analysis, display and perception, visualization, and computer-aided interpretation.

- G. **Imaging Agents and Molecular Probes.** Development and application of novel imaging agents and probes for clinical or pre-clinical applications. Examples of supported research include the development and application of quantum dots, nanoparticles, nanoshells, microbubbles, and radio-labelled contrast materials, and smart imaging agents that are bio-activatable or activated by other chemical, physical, or biological means.
- H. **Magnetic, Biomagnetic and Bioelectric Devices.** Development of magnetic, biomagnetic and bioelectric devices, e.g., EEG, MEG, etc. Examples include (but are not restricted to) novel detectors, increased sensitivity and spatial resolution, improved reconstruction algorithms, multiplexing with other imaging techniques, etc.
- I. **Magnetic Resonance Imaging and Spectroscopy.** Development of MR imaging and MR spectroscopic imaging, for both animal and human research, and potential clinical applications. Examples include (but are not restricted to) fast imaging, high field imaging, design of novel RF and gradient coils, novel pulse sequences, design of novel contrast mechanisms, imaging informatics, *in vivo* EPR imaging, molecular imaging, etc. The emphasis should be on technological development rather than detailed applications to specific diseases or organs.
- J. **Mathematical Modeling, Simulation and Analysis.** Development of mathematical models and computational algorithms with potential clinical or biomedical applications, including multi-scale modeling, modeling at or above the cellular level, and modeling at subcellular level, including those developed to support technology development in other program areas related to the NIBIB mission. Research that is funded includes studies that focus on the development of algorithms, mathematical models, simulations and analysis of complex biological, physiological, and biomechanical systems and use genomics and proteomics.
- K. **Medical Devices and Implant Science.** Design, development, evaluation and validation of medical devices and implants. This includes exploratory research on next generation concepts for diagnostic and therapeutic devices; development of tools for assessing host-implant interactions; studies to prevent adverse events; development of predictive models and methods to assess the useful life of devices; explant analysis; improved *in vitro* and animal models for device testing and validation.
- L. **Micro- and Nano-Systems, Platform Technologies.** Development of BioMEMS, microfluidics and nanoscale technologies, including micro-total analysis systems, arrays, and biochips, for detection and quantitation of clinically relevant analytes in complex matrices. Application areas include biomedical research, clinical laboratory diagnostics, biodefense, high-throughput screening, drug delivery, tissue engineering, and implantable devices, among others.
- M. **Nanotechnology.** Research and development of new enabling technologies for the fabrication and use of nanoscale components and systems in diagnostic and therapeutic applications. Examples include: development of new nanoscale patterning and manipulation systems; new approaches to the sensing and quantification of biologically important molecules using nanoscale specific properties; studies relating to the safety and commercialization of nanotechnology-enabled biomedical products.
- N. **Nuclear Medicine.** Research and development of technologies that create images out of the gamma-ray or positron (and resulting photon) emissions from radioactive agents that are injected, inhaled, or ingested into the body and then concentrate in specific biological compartments. Two particularly active areas are the wedding of positron emission tomography (PET) and single photon emission computed tomography (SPECT) to CT and/or to MRI, and the design of higher resolution, lower cost PET and SPECT devices for the study of molecular probes in small animals. Other topics of interest include the development of better radiopharmaceuticals, crystal scintillators, and collimators, and novel approaches to dual-isotope imaging and to dosimetry.
- O. **Optical Imaging and Spectroscopy.** Development and application of optical imaging, microscopy, and spectroscopy techniques; and development and application of optical imaging contrasts. Examples of research areas include fluorescence imaging, bioluminescence imaging, OCT, SHG, IR imaging, diffuse optical tomography, optical microscopy and spectroscopy, confocal microscopy,

- multiphoton microscopy, flow cytometry, development of innovative light sources and fiber optic imaging devices.
- P. **Sensors.** Development of sensor technologies for the detection and quantitation of clinically relevant analytes in complex matrices. Application areas include (among others) biomedical research, clinical laboratory diagnostics, and biodefense, covering *in vitro* diagnostics, noninvasive monitoring, and implantable devices. Technologies encompassed include novel signal transduction approaches, materials for molecular recognition, biocompatibility, signal processing, fabrication technologies, actuators, and power sources.
- Q. **Structural Biology.** Development of structural biology techniques, including (but not restricted to) solid state NMR, EPR, synchrotron radiation, etc. The emphasis is on technological development, rather than applications to specific structural biology problems.
- R. **Surgical Tools and Techniques.** Research and development of new medical technologies to improve the outcomes of surgical interventions. Examples of relevant technologies include: minimally invasive surgeries, energy-based interventions such as RF ablation, robotically assisted surgical systems, integration of imaging and interventional modalities, image guided interventions and telehealth.
- S. **Telehealth.** Development of software and hardware for telehealth studies that have broad applications as well as early stage development of telehealth technologies that may have specific focus areas. Research that is supported includes methods to address usability and implementation issues in remote settings, and methods to develop technology for standardizing and incorporating state of the art security protocols for verifying user identities and preserving patient confidentiality across remote access.
- T. **Tissue Engineering and Regenerative Medicine.** Development of enabling technologies including real-time, non-invasive tools for assessing the function of engineered tissues; real-time assays that monitor the interaction of cells and their environment at the molecular and organelle level; predictive computational models for engineering function 3D tissues; high-throughput assays and instruments to reduce the cost, time, and complexity of tissue engineering; novel bioreactor techniques for expanding stem cells and growing tissues and organs on a large scale; and strategies for preserving, sterilizing, packaging, and transporting living-tissue products. The program also supports applications of rational engineering design principles to functional engineered tissues; the development of novel biomaterials for use as tissue scaffolds that mimic the extracellular matrix and support multiple cell types in defined spatial orientation; and engineering approaches to study how biomaterials interact with cells and guide cell growth, differentiation, and migration.
- U. **Ultrasound.** Improvement of technologies for diagnostic, interventional and therapeutic uses of ultrasound. The diagnostic ultrasound program includes, but is not limited to the design, development and construction of transducers, transducer arrays, and transducer materials, innovative image acquisition and display methods, innovative signal processing methods and devices, and optoacoustic and thermoacoustic technology. It also includes the development of image-enhancement devices and methods, such as contrast agents, image and data presentation and mapping methods, such as functional imaging and image fusion. The interventional ultrasound program includes the use of ultrasound for therapeutic use, or as an adjunct for enhancement of non-ultrasound therapy applications. Examples include, but are not limited to, high-intensity focused ultrasound (HIFU) as a non-invasive or minimally invasive interventional surgical or therapy tool, and as an adjunct interventional tool. It also includes the use of ultrasound contrast agents for therapy and for targeted drug delivery, and the use of ultrasound for image-guided surgery, biopsy, and other interventions.
- V. **X-ray, Electron, and Ion Beam.** Enhancement of computed tomography (CT), computed radiography (CR), digital radiography (DR), digital fluoroscopy (DF), and related modalities. Research areas of support include the development of: flat panel detector arrays and other detector systems; flat-panel CT; CT reconstruction algorithms for the cone-beam geometry of multi-slice CT;

approaches to radiation dose reduction, especially with CT; and novel x-ray applications, such as those utilizing scattered radiation, tissue-induced x-ray phase shifts, etc.

For additional information on research topics, contact:

Mr. Todd Merchak
National Institute of Biomedical Imaging and Bioengineering
301-496-8592, Fax: 301-480-1614
Email: merchakt@mail.nih.gov

For administrative and business management questions, contact:

Ms. Florence Turska
National Institute of Biomedical Imaging and Bioengineering
301-496-9314, Fax: 301-480-4974
Email: turskaf@mail.nih.gov

NATIONAL CANCER INSTITUTE (NCI)

The goal of the NCI is to improve the current state of cancer care through advances in cancer research as well as enhancements in the prevention, diagnosis, and treatment of this disease. The Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) Programs are NCI's engines of innovation for developing and commercializing novel technologies to better prevent, diagnose, and treat cancer while enhancing cancer research and control. NCI's SBIR and STTR Programs offer funding for therapeutic agents and devices, *in vitro* diagnostics, imaging, cancer prevention, cancer biology, cancer control and epidemiology, e-Health, and many more areas of interest to the NCI.

NCI's SBIR and STTR programs focus on research, development and delivery and are critical to achieving the institute's goals. These programs fund small business concerns to conduct innovative cancer research and development. The NCI SBIR Development Center is committed to helping small business concerns advance promising technologies towards the marketplace through grant funding as well as its initiatives designed to facilitate external investments and commercialization. NCI encourages all SBIR Phase II awardees to apply to the [NIH Commercialization Assistance Program \(CAP\)](#) to gain assistance in transferring their products to the marketplace. NCI 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 the ability to develop products but also growth towards independence from the SBIR/STTR program.

The major NCI SBIR-STTR portfolio areas are listed below as a guide to general technology areas funded through the program. Applications proposing innovative cancer-related technologies, with strong commercial potential, that fall outside these topic areas are also invited through this omnibus solicitation.

Major NCI SBIR Portfolio Areas:

- Therapeutics (Small Molecules and Biologics)
- *In Vitro* Diagnostics
- Imaging Agents and Technologies
- Cancer Control and Digital Health
- Devices for Cancer Therapy
- Tools for Cancer Biology Research

For additional information on high priority technology areas, events, and programmatic initiatives, access the NCI SBIR homepage: <http://sbir.cancer.gov/>. In addition, please see the contact list at the end of the NCI section to identify the Program Director within the NCI SBIR Development Center who specializes in your technology area.

Limited Amount of Award

For budgetary, administrative, or programmatic reasons, NCI may not fund an application or may decrease the length of an award and/or the budget recommended by a review committee. Generally, NCI does not fund Phase I applications greater than \$300,000 total costs or project periods greater than 2 years; generally, NCI does not fund Phase II applications greater than \$2,000,000 total costs or project periods greater than 3 years. Applicants considering a requested budget greater than these limits are strongly encouraged to contact program staff before submitting an application.

Phase IIB SBIR Competing Renewal Awards

The NCI does not accept applications for Phase IIB SBIR competing renewal award through this solicitation. However, the NCI offers Phase IIB opportunities in the form of the NCI SBIR Bridge Award, which is announced via a separate funding solicitation. The SBIR Bridge Award is designed to support the next stage of development for previously funded NIH-wide SBIR Phase II projects in the areas of cancer therapeutics, imaging technologies, interventional devices, diagnostics and prognostics. The purpose of this award is to address the funding gap known as the "Valley of Death" between the end of the SBIR Phase II award and the subsequent round of financing needed to advance a product or service toward commercialization. To achieve this goal, the Bridge Award funding opportunity is specifically designed to incentivize partnerships between NIH's SBIR Phase II awardees and third-party investors and/or strategic partners. Competitive preference and funding priority will be given to applicants that demonstrate the ability to secure substantial independent third-party investor funds (i.e., third-party funds that equal or exceed the requested NCI funds).

Budgets up to \$1 million in total costs per year and project periods up to three years (a total of \$3 million over three years) may be requested from the NCI. Development efforts may include preclinical R&D needed for regulatory filings (e.g., IND or IDE) and/or clinical trials. NCI intends to commit up to \$10M for up to 10 new awards in FY2012.

To ensure that you will be notified upon the release of the NCI SBIR Bridge Award solicitation, please sign up for the [NCI mailing list](#). If you have any questions regarding the Bridge Award, please contact your Phase II program director.

For additional information on research topics, please contact a Program Officer with a relevant area of expertise:

Michael Weingarten, MA
Director, NCI SBIR Development Center
National Cancer Institute
6116 Executive Boulevard, Room 402, MSC 8332
Rockville, MD 20852
Email: weingartenm@mail.nih.gov

Web site: <http://sbir.cancer.gov>

Ali Andalibi, PhD
Program Director and Team Leader
Small Business Innovation Research Development Center (SBIR)
National Cancer Institute
6116 Executive Boulevard, Room 402, MSC 8332

Rockville, MD 20852

Email: andalibia@mail.nih.gov

Area of expertise: Biologics, Small Molecules and Therapeutic Surgical Interventions

Gregory Evans, PhD

Program Director and Team Leader

Small Business Innovation Research Development Center SBIR)

National Cancer Institute

6116 Executive Boulevard, Room 402, MSC 8332

Rockville, MD 20852

Email: evansgl@mail.nih.gov

Area of expertise: Cancer Imaging, Cancer Control, and Digital Health

Andrew Kurtz, PhD

Program Director

Small Business Innovation Research Development Center (SBIR)

National Cancer Institute

6116 Executive Boulevard, Room 402, MSC 8332

Rockville, MD 20852

Email: kurtza@mail.nih.gov

Area of expertise: Biologics, Small Molecules, Nanotherapeutics, and Molecular Diagnostics

David Beylin, MS, MBA, DABSNM

Program Director

Small Business Innovation Research Development Center (SBIR)

National Cancer Institute

6116 Executive Boulevard, Room 402, MSC 8332

Rockville, MD 20852

Email: beylind@mail.nih.gov

Area of expertise: Cancer Imaging, Radiation Therapy and Image-Guided Interventions

Patricia Weber, DrPH

Program Director

Small Business Innovation Research Development Center (SBIR)

National Cancer Institute

6116 Executive Boulevard, Room 402, MSC 8332

Rockville, MD 20852

Email: weberpa@mail.nih.gov

Area of expertise: Digital Health, Epidemiology, Software Development related to Cancer Control & Population Sciences, and Therapeutics

Xing-Jian Lou, PhD

Program Director

Small Business Innovation Research Development Center (SBIR)

National Cancer Institute

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Rockville, MD 20852

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Area of expertise: *In Vitro* Diagnostics and Bioinformatics

Deepa Narayanan, MS, CCDM

Program Director

Small Business Innovation Research Development Center (SBIR)

National Cancer Institute

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Rockville, MD 20852

Email: Deepa.Narayanan@mail.nih.gov

Area of expertise: Cancer Imaging, Radiation Therapy, and Clinical Trials

Amir Rahbar, PhD, MBA

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Small Business Innovation Research Development Center (SBIR)

National Cancer Institute

6116 Executive Boulevard, Room 402, MSC 8332

Rockville, MD 20852

Email: amir.rahbar@nih.gov

Area of expertise: *In Vitro* Diagnostics, Biologics, Therapeutics and Proteomics

Todd Haim, PhD

Program Manager

Small Business Innovation Research Development Center (SBIR)

National Cancer Institute

6116 Executive Boulevard, Room 402, MSC 8332

Rockville, MD 20852

Email: Haimte@mail.nih.gov

Area of expertise: *In Vitro* Diagnostics and Therapeutics

For administrative and grants management questions, contact:

Mr. Allen Lo

Grants Management Specialist

MSC 7150

6120 Executive Blvd

Rockville, MD 20892-7150

(301) 496-8796 Fax: 301-496-8601

Email: loa2@mail.nih.gov

For NCI-related SBIR Information, visit: <http://sbir.cancer.gov>.

***EUNICE KENNEDY SHRIVER* NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT (NICHD)**

The mission of the NICHD is to ensure that every person is born healthy and wanted, that women suffer no harmful effects from reproductive processes, and that all children have the chance to achieve their full potential for healthy and productive lives, free from disease or disability, and to ensure the health, productivity, independence, and well-being of all people through optimal rehabilitation.

For additional information about research areas of scientific interest to the NICHD, please visit our home page at <http://www.nichd.nih.gov>.

Phase IIB Competing Renewal Awards

NICHD will accept Phase IIB SBIR Competing Renewal grant applications to continue the process of developing products that require approval of a Federal regulatory agency (e.g., FDA, FCC). Such products include, but are not limited to: medical implants, drugs, vaccines, and new treatment or diagnostic tools that require FDA approval. This renewal grant should allow small businesses to get to a stage where interest and investment by third parties is more likely. Applicants who received NICHD SBIR Phase I or Phase II support and who are currently Phase II awardees are eligible. Budgets for Phase IIB

renewals should not exceed 3 million dollars total costs for three years. Depending on the research proposed the amounts may vary each year for the time requested.

You are strongly encouraged to contact Dr. Louis Quatrano (contact information provided below) before beginning the process of putting a Phase IIB Competing Renewal application together. Prospective applicants are strongly encouraged to submit to the program contact a letter of intent that includes the following information:

- Descriptive title of the proposed research
- Name, address, and telephone number of the Principal Investigator
- Names of other key personnel
- Participating institutions
- Funding Opportunity Announcement Number (e.g., PA-12-XXX)

Although a letter of intent is not required, is not binding, and does not enter into the review of a subsequent application, the information that it contains allows NIH staff to estimate the potential review workload and plan the review. It is expected that only a portion of NICHD SBIR/STTR Phase II awards will be eligible for a Phase IIB Competing Renewal grant.

Examples of research that would be considered responsive to this announcement are listed below for illustrative purposes and are not exclusive of other appropriate activities. Preclinical studies, including pharmacology and toxicology, and other clinical studies beyond those conducted under the initial Phase II (R44) grants such as:

- innovative assistive devices and techniques to minimize residual disability and to impact on critical illness, physical behavior and cognitive development in childhood;
- novel assays, kits, and devices to monitor fertility;
- new and improved methods of fertility regulation, for men and for women, that are safe, effective, inexpensive, reversible, and acceptable;
- new tools to monitor the state of various organ systems during therapy in pregnancy or infancy; and,
- Evaluation of neuroimaging tools specific to brain development in pediatric populations or individuals with injuries.

Direct your questions about scientific/research issues to:

Louis A. Quatrano, Ph.D.
Eunice Kennedy Shriver National Institute of Child Health and Human Development
301-402-4221, Fax: 301-402-0832
Email: Quatranol@mail.nih.gov

Population Research

Research on topics in reproductive sciences, contraceptive development, and demographic and behavioral sciences. Examples of research topics that may be of interest to small businesses include, but are not limited to:

- A. **Reproductive Sciences.** Research on the reproductive processes of men and women and of animals with similar reproductive systems related to developing safer and more effective means of regulating, preserving or achieving fertility. Particular areas of programmatic interest relative to small business initiatives include, but are not limited to:

- Development of reagents to facilitate study of reproductive and developmental processes.
- Development of improved methods of growing and differentiating stem cell lines *in vitro*, including feeder cell-free approaches.
- Development of novel assays, kits, and devices to monitor fertility and treat infertility and gynecological disorders.
- Use of genomics and proteomics to develop novel diagnostics and treatments for reproductive diseases and disorders.
- Development of high resolution technologies to provide invasive or noninvasive assessments of reproductive and developmental competence.
- Development of experimental animal models that would be useful for studying the physiology and pathophysiology of reproductive processes.
- Development of improved and novel technologies for the preservation of human gametes.
- Development of improved technologies for preimplantation genetic diagnosis.
- Development of improved technologies for the reprogramming of cells, including embryonic stem cells or adult cells, into eggs and sperm.

Dr. Stuart Moss
301-435-6979, Fax: 301-496-0962
Email: Mosstva@mail.nih.gov

- B. **Contraception and Reproductive Health Research.** Emphasis is on developing new and improved methods of fertility regulation; developing new and improved treatments for disorders of the reproductive system including female pelvic floor disorders; and research on the benefits and risks of contraceptives and other drugs, devices, and surgical procedures as they affect reproductive health. Areas of interest include, but are not limited to:
- Developing new and improved methods of fertility regulation, for men and for women that are safe, effective, inexpensive, reversible, and acceptable. This includes, but is not limited to, synthesis and testing of novel chemical compounds.
 - Developing new and improved treatments for disorders of the male and female reproductive system, including those used for hormone therapy and drugs, graft materials, and devices used for non-surgical and surgical treatment of pelvic organ prolapse, urinary incontinence, and other female pelvic floor disorders.
 - Discovering and disseminating new knowledge about the medical benefits and risks of contraceptives and other drugs, devices, and surgical procedures affecting reproductive health. We will primarily support applied research projects such as epidemiologic studies or Phase III trials designed to detect clinically significant adverse effects, particularly those too rare to be determined through the FDA's premarketing approval process. Laboratory models will be used when human studies are not feasible or to explore mechanisms of action or supplement epidemiologic and clinical observations.
 - Studies relating contraception or reproductive health to STDs such as HIV, including but not limited to development of new contraceptive products with microbicidal activity against STDs such as HIV; studies to define the relationships among contraceptive methods and HIV acquisition, transmission, or disease progression; and studies to clarify mechanism of interaction between contraceptives and other disease processes or conditions.

Dr. Steven Kaufman
301-435-6989, Fax: 301-480-1972
Email: Kaufmans@exchange.nih.gov

- C. **Demographic and Behavioral Sciences.** Research on the size, growth, and composition of populations and the impact of changes in population on the health and well-being of individuals, families, and the population itself. The program emphasizes not only factors affecting fertility, mortality, population movement and compositional change, but also demographic, social, and behavioral research on teenage childbearing, AIDS, single-parent families, fatherhood, racial and ethnic differentials in infant mortality and child health, migration, and the well-being of children. Applications are encouraged, but are not limited to these areas:
- Technological innovations/inventions to help collect biomarker data, especially technologies that can be used in large surveys.
 - Creation of hardware/software to aide in the collection of accurate cause of death/health diagnosis for the purposes of statistical analysis in population based datasets.
 - Innovative use/implementation in integrating geographical information systems, spatial network analysis, and/or simulation methods for demographic research.
 - Innovative approaches to analyzing and disseminating large-scale data sets.
 - Development of effective tools for prevention research and intervention programs related to STD/HIV, pregnancy, divorce, child health, at risk youth, and other health-related topics.
 - Innovative approaches to teaching population studies and other behavioral and social sciences at the undergraduate and graduate level.
 - Innovative approaches for research design, data collection techniques, measurement, and data analysis techniques in the social and behavioral sciences, with particular attention to methodology and measurement issues in studying diverse populations, sensitive behaviors, confidential behaviors; in issues related to the protection of research subjects; and in issues related to the archiving and disseminating complex datasets.

Dr. Abigail Haydon
301-496-1176, Fax: 301-496-0962
Email: Abigail.haydon@nih.gov

Research for Mothers and Children

Research in three major program areas includes: learning disabilities; cognitive and social development; nutrition and growth; obstetric and pediatric pharmacology, and pediatric, adolescent, and maternal AIDS. Topics that may be of interest to small businesses include, but are not limited to, those identified below.

- A. **Child Development and Behavior.** Research programs on psychological, social and emotional, psychobiological, and educational development from conception to maturity, specifically:
- Social and Affective Development, Child Maltreatment and Violence, including normative social, affective, and personality development and the impact of the physical and social environments on health and psychological development; investigations of socio-cultural, familial, individual, and biological influences on development; and child developmental processes in high-risk settings (e.g., in violent or abusive environments, or families experiencing stressors such as poverty, unemployment or parental depression).

- Developmental Cognitive Psychology, Behavioral Neuroscience, and Psychobiology, including linkages among developing brain, behavior, and genes; developmental pathways leading to normal and atypical brain development and behaviors and their underlying developmental mechanisms at the molecular, genetic, cellular and network levels; biological and behavioral indices of individual differences predictive of development at different points of development; neuroanatomical, neurofunctional, electrophysiological and neurochemical correlates of sensorimotor and cognitive abilities; tools to measure these; the effect of hormonal influences on behavioral development, including the development of gender-specific behaviors, the role of endocrines in social, emotional, and cognitive development, and the interaction of hormones and stress-related behaviors during development.
- Risk Prevention and Health Promotion: behavioral and developmental aspects of health risk behaviors and health promotion from infancy to young adulthood, including individual, interpersonal, and social factors; environmental and contextual factors; and interactions of genes and environment as they relate to health and health behaviors. Issues of risk behaviors, health literacy, adherence, pain, obesity, influence of electronic media, and influences of religiosity and spirituality are of interest.
- Reading, Writing, and Related Learning Disabilities: relative contributions of environmental, experiential, instructional, cognitive, linguistic, genetic, and neurobiological factors to the developmental reading process and to reading disabilities and writing, including the longitudinal course of development and the interactions among these factors at different stages of reading development, in both mono- and bilingual individuals; use of technology to facilitate development of reading and/or writing skills, these technologies could include but are not limited to assistive technologies, interactive technologies for use by children, adolescent or adult struggling learners as well as technologies for instructors, parents and/or caregivers for use within or outside of the classroom context, as appropriate.
- Language and Bilingualism: language development and disorders and second language acquisition, including studies within a developmental context, that identify and explicate the cognitive, linguistic, social, cultural, socioenvironmental, geographic, environmental, instructional, and neurobiological factors affecting the development of language abilities.
- Early Learning and School Readiness: experiences children need from birth to age eight to prepare them to learn, read, and succeed in school; early interactions with adults and peers; early childhood education teaching methods and curricula; comprehensive early childhood interventions that support learning and development; use of technology in promoting school readiness skills in disadvantaged children from birth to age six, including interactive technologies for use by parents, child care providers, and teachers and technologies for direct use by children.
- Math and Science Cognition, Learning and Learning Disabilities: mathematical thinking and problem solving; scientific reasoning, learning, and discovery; studies that explore the genetic and neurobiological substrates of normal and atypical development in mathematics and science learning and cognition, as well as cognitive, linguistic, sociocultural, and instructional factors; individual differences that may moderate achievement; the delineation of skill sets needed to attain proficiency; development of effective instructional methods for typical development and interventions for learning disabilities.

Dr. Peggy McCardle
301-435-6863, Fax: 301-480-7773
Email: pm43q@mail.nih.gov

- B. ***Endocrinology, Nutrition, and Growth.*** Research on the nutritional needs of pregnant women and their fetuses; aspects of nutrients related to reproduction, growth, and development; breast feeding and lactation; the immunology of breast milk; development of the gastrointestinal system; childhood

obesity and the nutritional antecedents of adult disease; developmental endocrinology; mechanisms of hormone action during growth and development, and the impact of hormonally active agents in the environment on growth and development. Applications to advance the study of obstetric and pediatric pharmacology include: Research and tools to better characterize the impact of physiological and developmental changes on pharmacokinetics and pharmacodynamics; advancements in modeling which improve therapy during pregnancy, among premature infants, children and adolescents; research on tools to monitor the state of various organ systems during therapy in pregnancy or infancy; such as, cerebral monitors, placental function, etc.; models to characterize molecular, dosing or other modification to improve therapy.

Dr. Gilman D. Grave
301-496-5593, Fax: 301-480-9791
Email: gg37v@mail.nih.gov

C. ***Pediatric, Adolescent, and Maternal AIDS.***

Domestic and international research on human immunodeficiency virus (HIV)/acquired immune deficiency syndrome (AIDS) in women of child-bearing age, pregnant women, mothers, fetuses, infants, children and adolescents. Specific areas of interest include but are not limited to epidemiology, clinical manifestations, pathogenesis, transmission, treatment and prevention of HIV infection, including prevention of mother to child transmission, and HIV-related complications in these populations. Additional areas of interest include:

- New technologies relevant to resource-limited countries for:
 - diagnosis of HIV infection in infants;
 - diagnosis and treatment of HIV-related complications of HIV (e.g., diagnosis of tuberculosis in children);
 - simple and less technical assays to monitor CD4 cell percentage/count, HIV viral load, or other surrogate markers of disease progression in children.
- Drug formulations for antiretroviral drugs and/or drugs used to treat complications of HIV infection relevant to children (preferably not liquid preparations), particularly in resource-limited countries and including fixed dose drug formulations and innovative methodologies for development of solid formulations capable of being administered to young children (e.g., sustained release beads, etc).
- Simple, standardized tools to evaluate neurodevelopmental outcome in children in resource-limited settings.
- Topical microbicide agents to prevent sexual acquisition of HIV in women or in adolescents.
- New, non-invasive technologies to evaluate complications of antiretroviral drugs in HIV-infected infants, children, adolescents (e.g., mitochondrial toxicity) and pregnant women, their fetuses and children.

Dr. Yasaman Shirazi
301-435-6871, Fax: 301-496-8678
Email: shirazi@nih.gov

Developmental Biology & Perinatal Medicine Research

Research in three major program areas includes: pregnancy and Perinatology; developmental biology, genetics and teratology; and mental retardation and developmental disabilities. Topics that may be of interest to small businesses include, but are not limited to, those identified below.

- A. **Pregnancy and Perinatology.** The topic areas of research include the physiology of pregnancy and labor; high-risk pregnancies, including those with hypertensive disorders, diabetes or seizure disorders; fetal pathophysiology; premature labor and birth; diagnostic, monitoring, and therapeutic devices and instruments for newborn infants in the nursery and in Neonatal ICU setting; improving the existing products or developing new products that would improve the routine and extended care of the newborn infants; products and agents related to breastfeeding; hospital supplies specifically related to use in the care of newborn infants; nanotechnology and its application for the care of newborn infants; instruments and devices assessing and monitoring the nursery environment (noise, lighting, and odor); disorders of the newborn; sudden infant death syndrome; and biological and behavioral antecedents of low birth weight.

The following topic areas are of high priority:

- Non-invasive methods for assessing cardiovascular and pulmonary functions, including cardiac output, systemic blood pressure, airway resistance, pulmonary compliance, vital capacity and various lung volumes.
- Metabolic profile assessment using non-invasive or minimally invasive approaches. Particular area of expertise include measurement of glucose and lactate/pyruvate; assessing ketone body measurements; free indirect bilirubin (unconjugated, free indirect); major chemicals (Na^+ Ca^+ Cl^+ K^+ etc.) in the blood.
- Improved point of care methods to measure plasma glucose concentrations quickly and accurately.
- Devices, instruments, and tools to minimize bacterial colonization, reduce proclivity for thrombous formation; reduce health-care associated infection risks.
- Rapid methods for diagnosis of bacterial infections and inflammation.
- Non-invasive measures to assess brain energy utilization, especially glucose, oxygen, lactate, ketones, and other energy substrates.
- Innovative ideas to reduce stress for the staff, parents and infants in the NICU.

Dr. Tonse Raju
301-496-5575, Fax: 301-496-3790
Email: rajut@mail.nih.gov

- B. **Developmental Biology, Genetics, and Teratology.** Biomedical research on the cellular, molecular, and genetic aspects of normal and aberrant embryonic and fetal development including early embryogenesis, organogenesis, limb regeneration, development of the nervous system, and causative factors in teratogenesis. Areas of interest include but are not limited to:

- development and application of new animal model systems
- innovative and high throughput genomic and proteomic techniques
- technologies to facilitate and advance systems biology approaches to the study of embryonic development and structural birth defects
- *in vivo* techniques for optical imaging and quantitative measurement of physical properties of cells/tissues
- innovative technologies for imaging of developmental processes and gene expression

Dr. Lorette Javois

301-496-5541, Fax: 301-480-0303

Email: lj89j@mail.nih.gov

C. ***Intellectual and Developmental Disabilities.*** Biomedical, behavioral and biobehavioral research in neuroscience, genetics, biochemistry, molecular biology, and psychobiology aimed at identifying factors that cause abnormal brain maturation and function; identification of direct and indirect environmental factors (e.g., social, economic and cultural) that influence the occurrence of intellectual and developmental disabilities (IDD); and research leading to the prevention, amelioration, assessment and treatment of IDD, including approaches that involve expanded newborn screening and prenatal diagnosis.

Dr. Tiina K. Urv

301-402-7015, Fax: 301-496-3791

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Medical Rehabilitation Research

This Center supports innovative research on the restoration, replacement, enhancement or adaptation of function for people with chronic physical disabilities. This includes rehabilitative approaches across etiologies and the lifespan, as well as the environmental and policy factors that promote full participation. We encourage studies that integrate biomedical, engineering and/or psychosocial approaches to develop practical and creative solutions to the daily functioning of people with disabilities and their families. The mission of the NCMRR is to increase the effectiveness of medical rehabilitation practices through research. Information about specific program areas within NCMRR can be found at:

<http://www.nichd.nih.gov/about/ncmrr/ncmrr.htm>. Examples may include but are not limited to:

- Systems Science - Develop methodologies/models for data to address the health trajectories from pathophysiology to participation in the rehabilitation process. Utilize methodology to understand whole body system responses to physical impairments and functional changes.
- Neuroplasticity - Develop non-invasive and surrogate measures of neuroplasticity that would be appropriate for use in a clinical setting to monitor rehabilitation treatment effectiveness.
- Rehabilitation Interventions - Develop Virtual Reality, simulations, e-health and other approaches to promote participation, understand and support healthy behaviors, reduce health disparities and enhance clinical compliance especially in children with disabilities
- Rehabilitation in the Community - Strategies to build or modify community resources that provide effective rehabilitation and health promotion services within the individual's own community.
- Novel Technology – Using nanomaterials, biomarkers, imaging, and robotics. to improve rehabilitation treatment for restoration of function. Develop techniques to improve/maximize parameters for trans-cranial magnetic stimulation.

Investigators proposing budgets exceeding the guidelines are encouraged to contact program staff six weeks prior to submitting the application.

For additional information on research topics, contact:

Nancy Shinowara, Ph.D.

301-495-6838, Fax: (302) 402-0832

Email: shinowan@mail.nih.gov

or

Louis A. Quatrano, Ph.D.

301-402-4221, Fax: 301-402-0832
Email: Quatranol@mail.nih.gov

Other Research Topic(s) Within the Mission of the Institute

For additional information on research topics, contact:

Louis A. Quatrano, Ph.D.
Eunice Kennedy Shriver National Institute of Child Health and Human Development
301-402-4221, Fax: 301-402-0832
Email: Quatranol@mail.nih.gov

For administrative and business management questions, contact:

Mr. Ted Williams
Grants Management Specialist
Eunice Kennedy Shriver National Institute of Child Health and Human Development
301-435-6996, Fax: 301-451-5510
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NATIONAL INSTITUTE ON DRUG ABUSE (NIDA)

The mission of the NIDA is to lead the nation in bringing the power of science to bear on drug abuse and addiction, through support and conduct of research across a broad range of disciplines and by ensuring rapid and effective dissemination and use of research results to improve prevention, treatment, and policy. For additional information about areas of interest to the NIDA, please visit our home page at <http://www.nida.nih.gov/>. SBIR and STTR programs at NIH are primarily intended to encourage private-sector commercialization of technology and to increase small business participation in federally funded R&D.

Both the SBIR and STTR programs consist of the three phases. During Phase I, NIDA supports the projects which establish the technical merit and feasibility of proposed research or R&D efforts and determines the quality of performance of the applicant (small business concern or SBC) before providing further Federal support in Phase II. During Phase II, NIDA supports the extension of the research or R&D efforts initiated in Phase I. Only Phase I grantees are eligible to receive Phase II funding. During Phase III, the small business concern (SBC) is to pursue commercialization with non-SBIR/STTR funds (either Federal or non-Federal). Applicants are encouraged to seek commitment(s) of funds and/or resources from an investor or partner organization for commercialization of the product(s) or service(s) resulting from the SBIR/STTR grant. Phase III funding may be from any of a number of different sources including, but not limited to: SBIR/STTR firm itself; private investors or “angels”; venture capital firms; investment companies; joint ventures; R&D limited partnerships; strategic alliances; research contracts; sales of prototypes (built as part of this project); public offering; state finance programs; non SBIR-funded R&D or production commitments from a Federal agency with the intention that the results will be used by the United States government; or other industrial firms. NIDA monitors SBC efforts to pursue, with non-SBIR/STTR funds, the commercialization of the results of the research or R&D funded in Phases I and II of the SBIR/STTR Program.

While making funding decisions, NIDA will carefully examine that proposed research has both the potential for commercialization and public benefit. NIDA funding decisions will be based on combination of factors: the review scores; the results of Phase I and the commercial potential and scientific/technical merit of the Phase II application (for Phase II applications); the quality of performance of the applicant, including the success in Phase III for the applicants with the previous history of SBIR/STTR support; programmatic priorities and portfolio balance; and availability of funds.

Special Features of NIDA SBIR Program

Fast-Track Applications

The NIH Fast-Track mechanism expedites the decision and award of SBIR and STTR Phase II funding by incorporating a submission and review process in which both Phase I and Phase II grant applications are submitted and reviewed together. The Fast-Track application will receive a single rating for the entire proposed project (i.e., it will receive a numerical score or it will receive an “unscored” designation). To be eligible for the Fast-Track option, the Phase I Research Plan must include well-defined, quantifiable milestones that should be achieved prior to initiating Phase II work. In addition, as is required for all Phase II applications, the Phase II portion of a Fast-Track application must present a Commercialization Plan. NIDA encourages Fast-Track mechanism for scientifically meritorious applications that have expressly high potential for commercialization, specifically. Applicants considering a Fast-Track application are strongly encouraged to contact program staff before submitting an application. Among the issues which potential Fast-Track applicants are encouraged to discuss with the NIDA program staff are: Value of the SBIR/STTR Project, Expected Outcomes, and Impact (the proposed project and its key technology objectives; the product, process, or service to be developed in Phase III; the need addressed, specifying weaknesses in the current approaches to meet this need; the commercial applications of the research and the innovation inherent in this application; the potential societal, educational, and scientific benefits of this work; the non-commercial impacts to the overall significance of the project); Market, Customer, and Competition (the market and/or market segments targeted, a brief profile of the potential customer, significant advantages SBC’s innovation will bring to the market, e.g., better performance, lower cost, faster, more efficient or effective, new capability, the hurdles to overcome in order to gain market/customer acceptance of the proposed innovation, any strategic alliances, partnerships, or licensing agreements already in place to market and sell the product, FDA approval (if required), marketing and sales strategy, overview of the current competitive landscape and any potential competitors over the next several years, etc.

Amount of Award

For budgetary, administrative, or programmatic reasons, NIDA may decrease the length of an award and/or the budget recommended by a review committee, or not fund an application. In general, NIDA advises to keep the amount of requested funds within \$150,000 - \$300,000 total cost per year for up to 2 years (Phase I) and up to \$1,000,000 total cost per year for up to 3 years (Phase II). 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

NIDA will accept SBIR/STTR Phase IIB Competing Renewal grant applications from Phase II SBIR/STTR awardees to continue the process of developing products that require approval of a Federal regulatory agency. Such products include, but are not limited to: drugs, vaccines, medical implants, or other treatment or diagnostic tools that require FDA approval. This renewal grant should allow small businesses to get to a stage where interest and investment by third parties is more likely.

Transitioning a new molecular entity from preclinical to the clinical phase of development, requires large-scale production of the new molecular entity and toxicity testing, activities which are both costly and time consuming. The cost and time constraints imposed by advanced stage development of a new molecular entity pose significant obstacles for small businesses. Although Phase I and Phase II SBIR support is sufficient for initial discovery efforts (e.g., compound synthesis and some *in vitro* and *in vivo* preclinical pharmacological testing), it is neither adequate to support necessary developmental preclinical work needed to comply with the FDA regulations, nor sufficient to conduct clinical trials.

The purpose of Phase II Competing Renewal Award is to provide Phase II awardees a chance for another three years of support. It is recognized that an award of this type may not support the entire medications development timeline for any given drug. The Competing Renewal grant will however, provide small

businesses with opportunity to further advance the development of its product /medication from the preclinical to the clinical stage, which will aid in attracting interest and investment by third parties, and provide an important sustained resource for new pharmaceuticals aimed at the safe and effective treatment of substance abuse.

Please contact Kris Bough (contact information provided below) before beginning the process of putting an application together. Prospective applicants are strongly encouraged to contact NIH staff prior to submission of a Phase IIB Competing Renewal application and to submit a letter of intent that includes the following information:

- Descriptive title of the proposed research
- Name, address, and telephone number of the Principal Investigator
- Names of other key personnel
- Participating institutions

Although a letter of intent is not required, is not binding, and does not enter into the review of a subsequent application, the information that it contains allows NIH staff to estimate the potential review workload and plan the review. It is expected that only a portion of NIDA SBIR/STTR Phase II awards will be eligible for a Phase IIB Competing Renewal grant.

The following examples would make appropriate topics for proposed SBIR or STTR Phase IIB Competing Renewal projects. These are meant for illustrative purposes only and are not exclusive of other appropriate activities.

Research and development efforts can be focused on medications for the treatment of cocaine, methamphetamine, and other stimulant abuse, as well as towards opiate, prescription opiates, cannabis, PCP or club drugs. The medications under development should be targeted towards attainment of abstinence and/or relapse prevention.

- Preclinical studies, including pharmacology and toxicology, beyond those conducted under the initial SBIR Phase I and Phase II grants. The studies conducted under the previous grants should be sufficient to provide a sound rationale for continued development of the entity or entities.
- Completion of studies as required by the FDA for an IND application.
- Human laboratory clinical trials to determine a medication's safety profile, metabolism, cardiovascular effects, interaction with drugs of abuse, etc.
- Clinical studies to assess the efficacy of the medication under development.

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Research Topics of Interest to NIDA

In this Omnibus Solicitation, NIDA emphasizes its need to discover, evaluate and develop medications (both small molecules and biologics) to treat substance use disorders (SUDs). NIDA further emphasizes an importance of fostering research through NIDA SBIR/STTR Program aimed at the research and development of medications for SUD, as well as research aimed at modernizing the drug discovery and development toolkit.

High programmatic priority will be given to research that seeks to achieve these goals in the following ways:

- 1) Drug discovery and development-enabling activities: Development of innovative technologies, methods or tools, including but not limited to:
 - Innovative *in vitro*, *in situ*, or *in vivo* tools for the molecular analysis of the central nervous system, normal and/or diseased.
 - Tools to simplify drug design through the use of advanced computing (simulation) methods.
 - Development of pre-clinical models for addiction.
 - Creation of a data repository / software tools for addiction-related clinical research data.
 - Novel analytical technologies and methods that enhance the understanding of basic mechanisms of drug action and improve drug testing; technologies designed to overcome the performance limitations of current drug discovery and development tools.
 - Technologies, including molecular imaging, gene expression profiling, and genotyping and sequencing approaches designed to better inform the diagnosis and treatment of substance use disorders
- 2) Drug discovery and development activities: Application of emerging and existing technologies and platforms to SUD drug development. This includes the identification, evaluation, development, approvability, and efficacy testing of new and improved pharmacotherapeutic agents, as well as the testing of marketed medications, and of behavioral treatments used alone or integrated with medications. Medical products with potential to minimize drug seeking, compulsive behavior, and/or addictive processes are strongly encouraged.
 - Chemistry / pharmaceutical drug development
 - Formulation and/or enhanced delivery of drugs
 - Preclinical and/or clinical drug development
 - Development of biomarkers related to treatment outcomes

Research Topics which are not aimed at development of medications for substance-use disorders or at modernizing the drug discovery and development toolkit, will have low program priority.

Specific projects could include:

Human Brain Neurochemical and Molecular Imaging. Measurement of brain neurochemistry, neuropharmacology (receptors) and gene expression in humans using non-invasive imaging has lagged behind advances in these areas in pre-clinical research as well as in functional and anatomical neuroimaging in humans. There is a continuing need for development of new ways to measure molecular targets in the human brain. Examples include, but are not limited to novel radioligands for PET and SPECT imaging in human brain for molecular targets (e.g., receptors, intracellular messengers, disease-

related proteins), as well as novel methods that use magnetic resonance imaging or other emerging technologies such as optical imaging.. The primary application of these methods will be in basic human research. Ultimately, these measures may also be used as potential biological markers and surrogate endpoints for translational and clinical research, drug discovery and development, and clinical trials. The scope of the projects may encompass pilot or clinical feasibility evaluation in pre-clinical studies, model development, or clinical studies. Alternatively, the focus may be on research and development of new technologies for molecular, neurochemical or neuropharmacological development.

Steven Grant, Ph.D. 301-443-4877; Email: sgrant@nida.nih.gov

Development of Assays for "Designer" Drugs of Abuse Based on Pharmacologic Activity Rather Than Chemical Structure. Contemporary illicit drug chemists have turned to the pharmacology literature to produce new "designer" drugs of abuse including (but not limited to) synthetic cannabinoid analogues found in "herbal incense" mixes or substituted cathinone stimulants sold as "bath salts". This new strategy has resulted in a diverse range of potential modified structures, all of which maybe pharmacologically active but each of which varies in molecular weight and substituents. This presents a substantial complication to traditional toxicology screens conducted in Emergency Rooms and to drug testing laboratories, whose assays rely on either immuno-assays or mass-spectrometry to detect specific agents. The current Funding Opportunity Announcement therefore aims to sponsor the development of assays based on pharmacologic activity rather than chemical structure.

Such assays should be:

- Non-invasive and able to detect quantities of illicit materials or metabolites in a range of concentrations typically found biofluids of substance users within a few days of use.
- Access to the biofluid samples should be minimally invasive and provide for temporal analysis. Such sample types include blood, urine, sweat and oral fluids.
- Assays should be designed with a standard clinical or analytical laboratory in mind, i.e., to be analyzed in a high throughput format by technicians with a moderate scientific training.
- The assays can be either designed to be analyzed with standard existing equipment, or include both the assay and development of analytical hardware, provided that the ultimate system can be commercially viable in a clinical and drug testing market place.
- Assays should be designed to remain relevant as illicit substance chemists adapt to legislation by altering pharmacophoric substituents such as side chains. Examples of such assays would include (but be not limited to) scintillation proximity assays, robust cell-based assays to detect pharmacology rather than a particular chemistry, or cells expressing engineered receptors activated solely by synthetic ligands, designed to pick up a range of metabolites. Other examples might include microfluidic surface plasmon resonance devices, which can both concentrate and detect receptor or antibody-bound substances.

Aidan Hampson, Ph.D. 301-443-8039; Email: aidan.hampson@nih.gov

Discovery of New Chemical Probes. SBIR applications are encouraged which propose to discover new chemical compounds as biological probes either by synthesis or isolation from natural resources in studying the mechanisms of action of drugs of abuse. Such substances could be new chemical compounds, drug products, or peptides. Currently there are several ligands available through the NIDA drug supply system such as SR 141716A, SR144528, CP 55,840, anandamide, epibatidine, Kaffiralin 1 and 2, etc. All probes for cannabinoids, neuropeptides, nicotinic acetylcholinergic receptors and related probes for drug abuse study are encouraged. In addition applications on biological screening of such new compounds as potential ligands for drug abuse research will also be considered.

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Nanoscience-based Design of Therapies for Substance Abuse Treatment. Nanoscience and nanotechnology, by manipulating matter at the atomic or molecular levels, are emerging research areas

that have the potential to fundamentally transform the study of biological systems and lead to the development of new methods for detection, prevention, and treatment of substance abuse and related disease states. NIDA invites nanotechnology-based applications in the following areas:

- a. Methods to enhance the efficacy of FDA-approved compounds by reducing their size to the nanoscale range to alter absorption, distribution, metabolism, or excretion.
- b. Development of new compounds, through manipulation of matter at the atomic or molecular levels that could more readily pass the blood-brain-barrier or cell membranes.
- c. Development of nanoscale particles for controlled targeted delivery of therapeutics, genes, or antibodies.
- d. Methods to enhance existing imaging technologies using magnetic properties at the nanoscale.
- e. Application of nanostructures (e.g. noble metal nanoparticles, quantum dots, and nanolithographic structures that show promise for diagnostic development) for identification and analysis of genes, proteins, and other biological molecules implicated in the actions of drugs of abuse.

Thomas G. Aigner, Ph.D. 301-435-1314; Email: ta17r@nih.gov

Drug Discovery – Chemistry and Pharmaceuticals. Within this area, NIDA supports research concerning the design (including molecular modeling and structure-activity relationship studies) and synthesis of novel compounds, formulation development, bioanalytical methods development, and pharmacokinetics/pharmacodynamics aimed at the discovery and development of novel medications for treating SUDs.

1. Synthesis or discovery of new chemical or natural compounds that would have potential as treatment agents for the medical management of SUDs. Consideration should be given to the design of partial agonists or pure antagonists that diminish the reinforcing effects of stimulants, as well as full agonists that could function to normalize physiological activity following discontinuation of stimulant use.

Compounds of interest particular include those that are designed to affect dopaminergic (e.g., D1 agonists, D3 agonists and D3 antagonists) activity, CRF antagonists, as well as those that affect glutamate activity, GABAergic activity, small molecule neuropeptide antagonists, and compounds acting through other mechanisms for which justification has been adequately supplied.

2. Synthesis (either using traditional or combinatorial techniques) of new chemical compounds that would have potential as treatment agents for the medical management of cannabinoid abuse.
3. Development of new immunotherapeutic treatments that would have the potential as treatment agents for stimulant or cannabinoid abuse.
4. Development of heroin/morphine-protein conjugates (heroin/morphine conjugate vaccines) for the treatment of heroin/opiate addiction.
5. Development of new approaches for the administration of potential addiction treatment drugs (including small molecules, natural products, peptides, proteins, antibodies, etc.) with poor bioavailability.
6. Development of controlled-release dosage forms for addiction treatment medications in order to maintain therapeutic drug levels for extended periods of time to alleviate compliance problems associated with addiction treatment.
7. Development of novel dosage forms or chemical/pharmaceutical approaches that eliminate or significantly reduce the abuse potential of prescription drugs/drug products.
8. Development of novel technologies and strategies to enhance delivery of potential therapeutic agents across blood brain barrier for the treatment of SRDs.

Preclinical Drug Development. Within this area, NIDA supports research on the development of preclinical behavioral models (e.g., of craving, drug-seeking behavior, dependence, or relapse), biochemical assays, gene expressional assays and electrophysiological methods to identify and characterize new medications to treat substance abuse, as well as pharmacological screening of novel compounds to identify potential drug abuse medications. This also supports research on toxicity studies of potential medications for the treatment of substance abuse, and interactions of potential treatment medications with abused substances. Areas that may be of interest to small businesses include, but are not limited to, development of new methods for discovery of medications useful in treating drug addiction. Of special interest would be the development of new animal models of addiction, incorporating established drug self-administration techniques that show increased relevance to the clinical setting. Development of relevant biochemical or electrophysiological screening methods is also encouraged.

Clinical Drug Development. Within this area, NIDA seeks to support the clinical development of compounds that have completed (or are nearing completion of) successful preclinical evaluation of a novel pharmacotherapeutic- or immunological treatment(s) for persons with SUDs. Products can be evaluated in any Phase of clinical development, I, II, or III. Treatments should aim to help subjects become drug free, mitigate drug use, prolong abstinence/reduce craving, and/or facilitate survival from drug overdose. Whereas it is expected that all clinical trials testing a novel medication will provide a behavioral therapy component, the scope of this funding announcement does not provide for the evaluation of the safety and/or efficacy of psychosocial interventions.

Therapies that a small business might consider developing include, but are not limited to:

- Repurposing of a compound developed for other indications (e.g., SSRIs, anti-epileptic drugs) that could be used to treat SUDs.
- A novel (e.g., NCE, novel drug formulation) that could be used to treat SUDs
- Vaccines for substances of abuse (e.g., cocaine, nicotine)
- Monoclonal antibodies for substances of abuse (e.g., methamphetamine, PCP)
- Naturally-occurring compounds (e.g., dietary supplements) that could be used to treat SUDs
- Or, a rationalized poly-therapeutic combination of pharmacotherapies designed to more comprehensively treat SUDs

Treatments that concurrently help alleviate associated psychiatric co-morbidities (e.g., depression, schizophrenia, PTSD, anxiety, etc.) and/or are focused upon underserved/vulnerable populations (e.g., pregnant women and their fetuses, adolescents, racial or ethnic minorities, women/gender issues, subjects within the criminal justice system) are also encouraged.

Also of special interest are products that incorporate technological advances to more efficiently develop novel therapeutics for SUDs, such as:

1. Improved methods to assess patient compliance during clinical trials (this can also include statistical modeling).
2. Improved adjuvants to boost antibody responses to drugs of abuse.
3. Discovery / development of biomarkers related to SUDs treatment outcomes. Because drug addiction is a brain disease which can change the structure and function of the brain, there is a unique opportunity to develop biomarkers that could reliably predict/assess SUD treatment outcome. To date, evaluations of SUDs often utilize subjective measures (e.g., patient-reported questionnaires) to assess disease progression and primary treatment outcomes. Biomarkers represent a more objective measure of physiological functioning that can be used to predict,

diagnose, evaluate the progression of, and/or more accurately assess overall treatment safety and effectiveness. The goal of this initiative is to support the small business discovery/development of reproducible, quantitative biomarkers related to SUD treatment outcomes. Potential biomarkers might be derived from underlying variations in DNA, gene expression, proteins, metabolism, and/or neuroimages, among others. This solicitation is open to fast-track applications.

4. Improved methods that can predict oral bioavailability of drug-like substances (*in vitro*; *in vivo*, *in silico*). For example, this might include the development of an innovative test /device that can be used to help more effectively diagnose and/or manage patients with SUDs. The use of this novel diagnostic tool might help to: (a) expedite the development of-, and/or (b) enhance existing treatments for patients with SUDs. Possible diagnostic tests/devices that a small business might consider, but are not limited to, include:
 - An assay/device (e.g., skin sensors, oral swabs) that detects a substance of abuse more reliably than oft-used urinalysis. Optimally, the analytical test/device would be non-invasive and easy-to-use, such that it could be used on an outpatient basis.
 - Discovery/development of a diagnostic test/screen that could help physicians more effectively manage treatments for patients with SUDs.

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NATIONAL INSTITUTE ON DEAFNESS AND OTHER COMMUNICATION DISORDERS (NIDCD)

The NIDCD supports research on the normal mechanisms of, as well as on diseases and disorders of hearing, balance, smell, taste, voice, speech and language. The Institute also supports research related to disease prevention and health promotion. The NIDCD addresses special biomedical and behavioral problems associated with people who have communication impairments or disorders. The NIDCD also supports efforts to create and refine devices, as well as develop cellular-based applications that may replace or substitute for lost and impaired sensory and communication functions. For more specific information about areas of interest to the NIDCD, please visit our home page at <http://www.nidcd.nih.gov/>.

Phase IIB Competing Renewal Awards

The NIDCD will accept Phase IIB SBIR/STTR Competing Renewal grant applications to continue the process of developing products that require approval of a Federal regulatory agency (e.g., FDA, FCC). Such products include, but are not limited to: medical implants, drugs, vaccines, and new treatment or diagnostic tools that require FDA approval.

The NIDCD will accept applications for up to two (2) years and up to \$750,000 per year in total costs. This renewal grant should allow small businesses to get to a stage where interest and investment by third parties is more likely.

Please contact your Program Director or Roger Miller, Ph.D., (NIDCD SBIR/STTR coordinator) before beginning the process of putting an application together. Prospective applicants are strongly encouraged to contact NIH staff prior to submission of a Competing Renewal application. Prospective applicants are strongly encouraged to submit to the program contact a letter of intent that includes the following information:

- Descriptive title of the proposed research
- Name, address, and telephone number of the Principal Investigator
- Names of other key personnel
- Participating institutions
- Funding Opportunity Announcement Number (e.g., PA-12-XXX)

Although a letter of intent is not required, is not binding, and does not enter into the review of a subsequent application, the information that it contains allows NIH staff to estimate the potential review workload and plan the review. It is expected that only a portion of NIDCD SBIR/STTR Phase II awards will be eligible for a Phase IIB Competing Renewal award.

Hearing and Balance Program

Research and development related to lost auditory function. Development of treatment modalities to prevent or lessen the effects of hearing disorders; development of new hearing aids, cochlear implants, and other assistive devices; development of systems designed to increase utilization of computers, telecommunication devices, or alerting systems by individuals with hearing impairments; development of improved screening technologies to assess hearing loss, especially in neonates and infants; development of new or improved batteries for hearing aids and or cochlear implants, including solar rechargeable devices; development of system on a chip technologies (e.g. DSP/VLSI/ASIC) to provide self fitting, self adjusting, or other features that increase performance, accessibility, or affordability of hearing aids; development of better earmolds to address allergy, occlusion effect and/or feedback complaints; development of new outcome measures for assessing the efficacy of treatments for hearing disorders; development of technologies for the study, diagnosis and treatment of tinnitus including development of neural prostheses to treat specific neural deficits; development of technologies for the study, diagnosis and treatment of otitis media including non-invasive diagnostics to identify middle ear pathogens, novel antibacterial strategies, and prophylactic anti-microbial strategies.

Research and development related to lost vestibular function. Development of tests and treatments for balance disorders, particularly for the elderly; development of clinical tests, instrumentation and software systems to assess balance/vestibular function, including otolithic functions and eye movements associated with the vestibulo-ocular reflex; development of instruments and tests measuring head stability and vestibular function during natural stimulation of the vestibular system including during locomotion; development of perceptual reporting techniques and psychological indices for the clinical assessment of the balance-disordered patient; development of tests and new outcome measures for assessing the efficacy of physical rehabilitative regimens for balance disorders; and development of assistive devices for balance disorders, including prostheses involving electrical stimulation of the vestibular system.

Development of new research tools to aid in the study of the auditory and/or balance systems including neuroimaging techniques (e.g. software tools, neuroanatomic tracer; optical and, multielectrode methods of assessing neural activity; new animal models of impaired function; diagnostic tools for inner ear function, including DNA-based assays and biochemical markers of disease. Development of improved tests and instruments for screening and diagnosis of inner ear function; development of technologies to enable gene transfer to the inner ear, including viral vectors; development of cell type specific markers and probes to examine cell lineage in inner ear regeneration; development of relevant software, including computational modeling tools, databases or web sites.

Roger L. Miller, Ph.D.

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Voice, Speech, and Language Programs

Research on voice, speech, and language disorders focuses on determining the nature, causes, treatment and prevention of communication disorders such as stuttering, spasmodic dysphonia, dysarthria, and aphasia. Emphasis is on research and development of diagnostic measures and intervention strategies for voice, speech, swallowing, and language disorders; development of communication and other assistive devices for individuals with voice, speech, swallowing, and language disorders; development of speech and language assessments and interventions for nonverbal autistic

individuals; development of new systems for visual communication by individuals who are deaf or severely hearing impaired; development of new systems of communication for individuals with motor speech impairment, including a brain computer interface (BCI) communication prosthesis; development of innovative treatment delivery systems or intervention protocols; design and development of diagnostic measures or materials for early identification of voice, speech and language impairment in children; development of assessments and treatments for childhood and adult voice, speech and language impairment in multi-cultural populations; development of assessment measures of sign language abilities; development of improved artificial larynges and tracheoesophageal shunts; development of artificial intelligence computer models that simulate normal and disordered voice, speech and language.

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Taste and Smell Program

Research on the development of easily administered diagnostic tools for testing human chemosensory function in population studies; epidemiological studies of the prevalence of taste and smell disorders; intervention strategies for smell and taste disorders; development of bitter taste-blockers targeted toward pharmaceuticals; the development of artificial sweeteners; influence of taste and smell haplotypes on chemosensory sensitivity; chemosensory stem cell biology; human pheromone detection; retronasal olfaction; high-throughput screening of putative chemosensory ligand-receptor interactions; olfactory biomarkers for neurodegenerative disease; chemosensory risk factors affecting diet and health; biosensors and electronic noses for medical and industrial applications; and the development of an inventory of chemicals at exceptional high purity.

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Other Research Topic(s) Within the Mission of the Institute

For additional information on research topics, contact:

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For administrative and business management questions, contact:

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NATIONAL INSTITUTE OF DENTAL AND CRANIOFACIAL RESEARCH (NIDCR)

The NIDCR conducts and fosters research on the etiology, pathogenesis, prevention, diagnosis, and treatment of oral, craniofacial and dental diseases and conditions. For more specific information about areas of interest to the NIDCR, please visit our home page at <http://www.nidcr.nih.gov>.

NIDCR's small business programs are highly focused on maximizing translational opportunities – moving rapidly and intentionally toward pushing innovation in basic orofacial biology into useful products. The following are areas of particular interest.

Developmental Biology and Mammalian Genetics

Emphasis is on the understanding of the development of tooth and bone, and on the identification of the genetic and environmental contributions to craniofacial disorders. The objective of this scientific program is to elucidate the underlying causes of craniofacial disorders, thereby advancing the fields of diagnosis, treatment, and prevention. Small business opportunities in this area include but are not limited to:

- A. Develop early pregnancy genetic tests to screen fetal cells in maternal blood for genetic mutations involved in inherited syndrome and non-syndrome craniofacial defects.
- B. Develop instrumentation to improve the diagnosis and treatment of inherited and acquired craniofacial defects.
- C. Develop improved appliances to aid suckling by newborn infants with cleft palate and cleft lip.

Infectious Diseases and Immunity

Research relating to the etiology, pathogenesis, prevention, diagnosis and treatment of infectious diseases of the oral cavity is supported by the NIDCR. This includes research on practical ways to effectively use the host immune system to prevent or treat oral infectious diseases and microbial-induced inflammation. Infectious diseases of the oral cavity include caries, periodontitis, candidiasis, peri-implantitis, pulpitis, and various viral, bacterial, and fungal infections of the oral mucosa and research on the diagnosis and prevention of oral manifestations and malignancies of HIV infection and AIDS. Specific examples of technology development needs include but are not limited to:

- A. Develop ways to overcome or eliminate the risk of oral infections in persons who smoke or chew tobacco, drink alcohol, or are immunosuppressed, have diabetes, are malnourished, or are psychologically stressed.
- B. Explore novel methods or agents to eradicate oral biofilms (dental plaque) on teeth, oral soft tissues, and dental implants without adversely affecting the normal oral flora.
- C. Isolate, synthesize or prepare new antibiotics and antimicrobial agents that can overcome bacterial and fungal resistance to current compounds. Formulate combinatorial drug regimens to attack microbes growing in oral biofilms (dental plaque).
- D. Develop controlled release systems for local delivery of synthetic peptides, recombinant proteins, or other chemical or immunotherapeutic agents to prevent, control, and/or treat oral infectious diseases, or the oral manifestations of HIV infection.
- E. Develop biological response modifiers or other immunological approaches to reduce or eliminate microbial-induced chronic inflammation or the tissue destruction associated with chronic inflammation in the oral cavity.
- F. Develop ways to interfere with microbial colonization and growth through the use of antimicrobial agents and chemotherapy.

- G. Identify and exploit the structural features of oral biofilms for increased therapeutics delivery.
- H. Develop computer programs and apply systems biology approaches to model biologically active peptide regions of oral components that have anti-fungal, anti-bacterial and anti-viral activities. Challenges appropriate for small business applications could include:
 - I. Develop substitutes of naturally occurring chemicals (phytochemicals) known to have a role in controlling opportunistic infections induced by HIV.
 - J. Develop synthetic peptides and recombinant proteins of oral components with anti-fungal, anti-bacterial and anti-viral activities including those against HIV and oral opportunistic pathogens.
 - K. Develop oral topical formulations with combined microbicidal, analgesic, and anti-inflammatory activities to enhance oral mucosal defenses and prevent and/or control oral infections and lesions in HIV-infected and/or immunosuppressed subjects.
 - L. Discover, test, standardize, and validate novel biomarkers present in oral fluids for screening and clinical diagnosis of HIV and oral opportunistic pathogens.

Clinical Research

Develop improved methods to detect and predict progression of dental caries, periodontal disease, reversible pulpitis and irreversible pulpitis.

Oral, Oropharyngeal and Salivary Gland Cancers

Emphasis is on molecular mechanisms of oral epithelial cell deregulation that lead to oral cancers. Research related to early detection, diagnosis, prevention, and treatment of oral cancers is of particular interest. Examples include but are not limited to the following areas:

- A. Develop imaging techniques for the early detection, diagnosis and prognosis of pre-malignant lesions.
- B. Develop effective pharmacological, immunological and radiological modalities for treatment of pre-malignant and malignant lesions.
- C. Develop novel technologies for the genetic and molecular-targeted therapy (e.g. siRNAs, peptide based therapies).
- D. Develop novel micro and nano-sensor technologies that can effectively release therapeutic agents to tumor tissues.
- E. Develop regimens for the alleviation of the oral complications of cancer therapy.
- F. Develop animal models to facilitate the testing of therapeutic and chemopreventive agents for oral cancers.

Temporomandibular Joint Disorder and Orofacial Pain

Emphasis on research for chronic disabling painful diseases of the oral-craniofacial-dental areas including chronic pain, neuropathies, and diseases of the temporomandibular joint. NIDCR encourages small business applications that include but are not limited to:

- A. Developing improved techniques for measuring nociceptive, chemosensory, tactile, kinesthetic, or proprioceptive function involving craniofacial structures. Such measures may be useful in screening for deficits, improving diagnosis, or for evaluating responses to orofacial treatments or interventions.
- B. Developing improved biomarkers for neuropathic conditions affecting oral-craniofacial tissues or structures.

- C. Developing assays facilitating reliable evaluations of relationships between biological and other risk factors as they relate to onset, and exacerbation of pain and for examining the transition from acute pain to chronic pain conditions.
- D. Discovering and developing novel, pharmacological medications for treating chronic orofacial pain disorders, by leveraging results from ongoing genetic studies of chronic pain conditions.

Saliva, Salivary Diagnostics, and Salivary Gland Diseases

Emphasis is on salivary gland physiology and pathophysiology and in the repair and restoration of the damaged gland. Examples of small business applications include but are not limited to:

- A. Development of viral, non-viral and gene therapy-based approaches to address compromised salivary gland function. Development of cell and tissue-based strategies and technologies for restoration of damaged or destroyed salivary gland function.
- B. Development of novel compounds or materials that protect and preserve salivary glands from head and neck cancer irradiation therapy.
- C. Development of non-invasive methods for the determination of efficacy and safety of artificial saliva, sialogogues, and of their delivery vehicles used in addressing the diminution or lack of saliva (xerostomia) due to Sjögren's Syndrome or head and neck cancer irradiation therapy.
- D. Development of biomarker strategies and technologies for the identification of Sjögren's Syndrome in blood or saliva.
- E. Discovery of biomarkers derived from oral fluids that are predictive of the onset, progression and recurrence of oral diseases and conditions, such as periodontal diseases, caries, and oral, oropharyngeal and salivary gland cancers.
- F. Development of immunological strategies and immunotherapy-based approaches for addressing xerostomia from Sjögren's Syndrome.
- G. Development of enhanced or novel tools for early detection of salivary gland cancers.
- H. Development of standardized methodologies for determining fluoride load from saliva, serum, urine, nails clippings, and hair.

Biotechnology, Biomaterials, and Applications for Regeneration and Restoration of Oral, Dental and Craniofacial Tissues

Emphasis is placed on the development of a broad range of technologies targeted at regeneration and restoration of diseased and injured hard and soft tissues of the oral and craniofacial complex and on translating these applications to the clinic. Tissues of interest include craniofacial and alveolar bone, the periodontal ligament, TMJ bone and cartilage, oral mucosa, facial skeletal muscle, vasculature and peripheral nerve. Also of interest are multi-tissue composites and organs, such as vascularized and innervated bone and muscle, salivary gland, tooth, periodontium, bone-periodontal ligament-cementum interface and osteochondral complexes. Specific examples of relevant small business applications could include but are not limited to:

- A. Development of technologies for design, fabrication, and manufacturing of biomimetic and biocompatible biomaterials and scaffolds, including nanomaterials and self-assembling nano-scaffolds, for tissue engineering and regenerative medicine applications.
- B. Development of cell-based technologies, including stem cell-based technologies. These include, designing strategies for isolation, purification, scaled up production, standardization, comparison and quality control of stem and progenitor cells and their differentiated progenies, derivation of efficient

and predictable methodologies for cellular reprogramming, and advancing technologies for reconstruction of stem cell niches for augmenting tissue regeneration.

- C. Development of bioreactor systems to facilitate design, fabrication, and manufacturing of soft and hard tissues. Among their capabilities, these bioreactors may be able to mimic biophysical forces, such as mechanical and electrical forces that normally guide tissue morphogenesis *in vivo*.
- D. Development of improved dental composite materials, including biomimetic and self-healing materials and adhesive sealants. These include but are not limited to materials to replace Bis-GMA resin-based systems that are suitable for restoring crowns of posterior teeth and exposed roots of the teeth.
- E. Development of methods, materials, and devices for orthodontic, prosthetic, and craniofacial applications including those that can be used for craniofacial bone distraction, craniofacial reconstruction, healing, and scarless repair.
- F. Development of artificial tissue and organ mimics that can be adapted to high-throughput formats for a broad range of screening applications, such as analysis of biomaterial and tissue function, drug efficacy and toxicology assays, biocompatibility assays, genetic screening and others.
- G. Development of mathematical, computational, and bioinformatics approaches for modeling oral and craniofacial tissues and organ function and physiology to address needs of system biology, synthetic biology, and single cell analysis.
- H. Development of novel biomolecules, including growth factors, cytokines, small molecules, siRNAs, and others for counteracting diseases and injuries of oral and craniofacial tissues and promoting their regeneration.
- I. Development of advanced viral and non-viral based biomolecule delivery technologies that can precisely deliver and release therapeutic proteins, nucleic acids, small molecules, or combinations thereof with predictable temporal kinetics to target specific tissue sites.
- J. Development of imaging diagnostics to accelerate clinical implementation of reliable, reproducible, highly specific and sensitive diagnostic instruments for dental caries, cracked teeth, pulp vitality and periodontal diseases.

Clinical and Behavioral Research

Provides support for the development of evidence-based products related to behavioral and social aspects of oral health, oral health prevention or treatment interventions, and other patient-oriented aspects of oral health. This includes support for clinical trials and patient-oriented research to establish safety and initial efficacy of products. NIDCR is especially interested in applications that significantly improve oral health by: 1) being broadly applicable to many populations, 2) contributing to meaningful oral health improvements for a specific population, 3) expediting translation of research findings into oral health improvements, and/or 4) equipping oral health care providers, educators or researchers with tools to improve public oral health. Examples of studies of interest include, but are not limited to, the following:

- A. Develop and test devices or methods to improve time-sampled monitoring of behavioral adherence with preventive or therapeutic regimens specifically relevant to oral diseases/conditions. Such devices or methods could be utilized in a variety of settings, including naturalistic settings, within clinical trials, within oral health care delivery systems, etc.
- B. Develop and test novel compliance and survey measures or tools to identify the underlying causes of insufficient preventive dentistry for specific underserved populations.
- C. Develop, or adapt for use in a new population or setting, novel measures or methods for identifying individual, family, group, or other processes that explain oral health behavior.

- D. Develop and test for safety, efficacy, and/or effectiveness of measures or materials for diagnosing, preventing, or treating oral, dental, and craniofacial conditions and disorders.
- E. Develop, or adapt for use in a new population or setting, oral health interventions utilizing technology to improve efficiency of delivery (e.g., management of chronic pain related to temporomandibular joint disorders, etc.).
- F. Develop, or adapt for use in a new population or setting, interventions addressing health behaviors highly associated with oral health (e.g., tobacco, alcohol, and other drug use; management of diabetes, HIV infection, or other chronic illnesses; etc.).
- G. Develop technologies or modules that utilize existing web-based platforms to improve preventive oral health hygiene for children and adolescents (e.g., social marketing via web-based interaction, virtual reality “worlds”, “massively multiplayer online games”, etc.).
- H. Develop and test innovative methods for facilitating collaborations, referrals, and/or ongoing follow-ups between oral health professionals and other health care professionals.
- I. Develop and test web-based training or other innovative approaches for oral health care professionals to accelerate accurate translation of new knowledge regarding oral diseases and their effective prevention or treatment into clinical or public health practice.
- J. Develop and test the effectiveness of innovative teaching tools to inform oral health professionals or the public regarding oral cancer prevention and early detection.

Other Research Topic(s) Within the Mission of the Institute

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NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES (NIDDK)

The NIDDK supports research in diabetes, endocrinology and metabolic diseases; digestive diseases and nutrition; and kidney, urologic and hematologic diseases. For additional information about areas of interest to the NIDDK, please visit our home page at <http://www.niddk.nih.gov>.

Phase IIB Competing Renewal Awards

NIDDK will accept Phase IIB SBIR/STTR Competing Renewal grant applications from NIDDK supported Phase II awardees that propose to continue the process of developing products that ultimately require 1) clinical evaluation, 2) approval by a Federal regulatory agency, and 3) continuing refinements to durable medical equipment (DME) designs such as cost reduction, testing for safety, durability, and reliability, and meeting or establishing standards. This renewal grant should allow small businesses to get to a stage where interest and investment by third parties is more likely. Such products include, but are not limited to biological products, devices, drugs, medical implants, etc. related to the mission of the NIDDK. The previously funded Phase II SBIR/STTR grant need not have been submitted in response to a particular solicitation, as long as the research is appropriate to the purpose of this solicitation. Budgets up to \$1,000,000 total costs per year and time periods up to 3 years may be requested for this Phase IIB Competing Renewal opportunity. These awards are intended to support completion of research needed to obtain an IND or IDE. Applicants must provide evidence that they have consulted formally with the FDA concerning the research needed for the development of a drug, biologic or medical device and that the proposed research will address these regulatory requirements. Such evidence should include FDA correspondence from a pre-IND meeting for an IND application or a pre-IDE meeting for an IDE application, and the status of the project in a timeline related to Federal regulatory approval processes.

Prospective applicants are strongly encouraged to contact NIH staff listed at the end of this NIDDK topics announcement prior to submission of a Competing Renewal application. Prospective applicants are strongly encouraged to submit to the program contact a letter of intent that includes the following information:

- Descriptive title of the proposed research
- Name, address, and telephone number of the Principal Investigator
- Names of other key personnel
- Participating institutions
- Funding Opportunity Announcement Number (e.g., PA-12-XXX)

Examples of research that would be considered responsive to this announcement are listed below for illustrative purposes and are not exclusive of other appropriate activities.

- Completion of studies as required by the Food and Drug Administration (FDA) for Investigational New Drug (IND) or Radioactive Drug Research Committee (RDRC) application.
- Assessment of devices with regard to performance standards related to the FDA approval process.
- Clinical and toxicology studies in support of an Investigational New Drug Application to the FDA.
- Clinical studies in support of Pre-Market Approval for biomarkers/medical devices by the FDA.

Diabetes, Endocrinology and Metabolic Diseases

The Division of Diabetes, Endocrinology and Metabolic Diseases supports basic and clinical research on the etiology, pathogenesis, prevention, diagnosis, and treatment of diabetes mellitus and its complications; endocrine diseases; osteoporosis; cystic fibrosis, and other metabolic disorders; as well as research on basic endocrine and metabolic processes. Research topics of potential interest to small businesses include, but are not limited to:

I. SENSORS AND DELIVERY DEVICES:

- A. Assessment of non-invasive, minimally invasive or implantable sensors for monitoring blood or interstitial fluid glucose for prevention of hypo- and hyperglycemia in diabetic patients. NIDDK will give priority to research that has already progressed to an *in vivo* model or to be clinically tested.
- B. Integration of glucose sensor and insulin delivery systems to create an artificial pancreas.
- C. Development of improved insulin delivery methods or devices.
- D. Development of novel and more accurate non-enzymatic based glucose detection technologies.
- E. Develop telemedicine approaches that can be incorporated as components/and or adjuvants of an artificial pancreas for better diabetes self management.
- F. Development of technologies that may promote and facilitate adherence/compliance by users of glucose control devices.

II. SCREENING TESTS, DIAGNOSTICS AND BIOLOGIC TOOLS:

- A. Development of techniques or products useful for predicting, preventing or delaying progression of diabetes, including tests for identifying patients at risk, and methods of monitoring disease progression.
- B. Development of diagnostic tools for diabetic foot ulcers. These tests could be used to determine the risk of developing a diabetic foot ulcer or used for choosing treatment strategies.
- C. Development of diagnostic tools to measure the autonomic neuropathy that develops in people with diabetes.
- D. Development of clinical measures of oxidative stress, advanced glycation end-products and chronic inflammation that result from diabetes.
- E. High throughput - Point of care technologies (reliable, accurate, cost-effective, highly sensitive, standardized having rapid turnaround time) for autoantibody detection, T cell –subsets-auto-reactivity and other immune parameters for autoimmune diabetes diagnosis and follow-up.
- F. Development of methods to measure changes in the immune status that may be used as markers to follow the immune-modulatory activity and beneficial effect (beta cell mass preservation, reduction of inflammation at the target organ, etc) of biologic agents tested in clinical trials for the prevention and/or treatment of T1D.
- G. Development of high throughput assays based on biologic pathways likely involved in the pathogenesis of diabetes and its complications that could be used to screen molecular libraries for novel therapeutic agents.
- H. Development and validation of surrogate markers to monitor disease progression and potential therapies for diabetic complications.
- I. Development and validation of tools for use by health care providers/systems to improve diabetes care and prevention.
- J. Development of techniques and tools to identify islet cell progenitors, methods to predict transplant success with recovered islet preparations, and non-invasive imaging as well as other methods for the *in vivo* measurement/ evaluation of pancreatic beta cell mass, function or inflammation after transplantation of pancreatic islet/beta cells.
- K. Point of care low cost /portable technologies for diabetes and pre-diabetes diagnosis.
- L. Development of Innovative technologies to predict and prevent hypoglycemia.

III. INTERVENTIONS AND THERAPIES:

Diabetes

- A. Development of immunomodulation/tolerance induction strategies to prevent or slow progression of type 1 diabetes.
- B. Development of new therapies or devices to prevent and treat diabetic foot ulcers.
- C. Development of new therapies to correct the underlying metabolic defects that result from diabetes, such as reactive oxygen species production and glycation of proteins.
- D. Development of methods that protect islet grafts after transplantation, including the evaluation of alternative transplantation sites, minimize the use of immunosuppression through immunomodulation/tolerance induction or immunoisolation/encapsulation of the graft from the host immune system, or support the use of single donors for transplantation.
- E. Development of methods that expand the number of human islets during culture while still retaining appropriate functional islet characteristics and the ability to be successfully transplanted.
- F. Development of methods utilizing replenishable cell sources, especially stem cells that produce functional islet like cells/tissues that can be successfully transplanted.
- G. Development of more reproducible methods that improve yield/viability/function of islets prior to transplantation and the engraftment and long term function of islets after transplantation.
- H. Development of educational or psychosocial approaches that increase adherence to recommended diabetes treatment regimens or that reduce co-morbidities and complications (e.g., depression or foot ulcers).
- I. Development of novel technologies that may facilitate self management of diabetes and adherence to treatment.
- J. New implantable and easy to replace technologies that may mimic the beneficial effect of gastric bypass/bariatric surgery for the treatment of diabetes without the need of a major invasive surgical procedure.

Other Endocrine and Metabolic Disorders

- K. Identification of new ligands for previously unclassified (orphan) nuclear receptors and development of partial agonists or antagonists with therapeutic potential for diseases such as diabetes and osteoporosis, hormone-dependent cancers, and for conditions such as obesity.
- L. Development of Selective Receptor Modulators (SRMs) with tissue specificity and profiles that provide beneficial effects without the side effects secondary to therapies based on naturally occurring hormones.

IV. GENETIC TESTING AND GENETIC THERAPIES

- A. Development of improved methods for the diagnostic, population or newborn screening or prenatal testing for genetic metabolic diseases.
- B. Improvements in the construction of gene therapy vectors to increase transduction efficiency, level and duration of expression, and to improve targeting.
- C. Development of improved methods of manufacturing gene therapy vectors that are scalable and improve titer and bioactivity of the vectors.
- D. Development of new vector systems that improve the ability to transduce nondividing cells such as hematopoietic stem cells, neurons, hepatocytes or epithelial cells.
- E. Development of techniques to achieve efficient homologous integration or site-specific integration of introduced genes.

Digestive Diseases and Nutrition

The Division of Digestive Diseases and Nutrition supports research on the function, diseases and disorders of the digestive tract; the esophagus, stomach, intestine, colon, anorectum, pancreas, liver, gallbladder, and biliary tract; basic, clinical and behavioral research on nutrition and obesity as well as information transfer in the field of digestive diseases and prevention of obesity. Innovative investigator-initiated projects that are not mentioned below are encouraged. Areas that may be of interest to small businesses include, but are not limited to:

I. DIGESTIVE AND LIVER DISEASES (CLINICAL)

- A. Development of assays and new genetic screening methods for detection of biomarkers for genetic predisposition to GI-relevant diseases, e.g., IBD, hemochromatosis, Wilson's disease.
- B. Development of improved means for detecting Barrett's esophagus.
- C. Development of methods for gastrointestinal endoscopy without the need for sedation.
- D. Development, using rational drug design techniques, of agents that interact with L-type calcium channels or with delayed rectifying potassium channels to treat motility disorders (pseudo-obstructive disorder, chronic constipation, and slow bowel transit).
- E. Development of novel antifibrotic therapies for progressive liver failure.
- F. Development of agents that would protect the gut epithelium from the damage caused by chemotherapeutic agents.
- G. Development of quantitative tests of hepatic "reserve" which would be of use, for example, in assessing the risk of surgery in patients with liver disease.
- H. Development of agents to promote the repair of gut epithelium barrier function, e.g., as needed following chemotherapy.
- I. Development of humanized monoclonal antibodies against HCV and HBV to be used for prevention of recurrent disease in liver transplant patients.
- J. Development of surrogate markers and non-invasive imaging methods to quantitatively assess liver fibrosis, inflammation, and fat that accurately assesses progression in patient.
- K. Development of a rapid, diagnostic test for biliary atresia.
- L. Develop and validate therapeutic interventions for treatment and/or progression of pancreatitis and its complications.
- M. Develop novel and more effective pharmacologic and/or endoscopic approaches to prevent ERCP-induced pancreatitis.
- N. Develop more accurate and useful approaches to the diagnosis of chronic pancreatitis by functional, radiologic, endoscopic, or pathologic/cytologic means.
- O. Develop gastrointestinal endoscopic instruments that have improved visualization and therapeutic capabilities for detecting mucosal abnormalities and pathologies and providing improved interventional capabilities.

II. DIGESTIVE AND LIVER DISEASES (BASIC)

- A. Development of detection methods for non-culturable forms of gut enteric bacteria.
- B. Development of molecular probes for the diagnosis of mucosal dysplasia in inflammatory bowel disease.
- C. Development of gut immune-modulators, or non-antigenic gliadin in celiac disease.

- D. Development of new techniques, including non-invasive imaging, to measure motility/intestinal transit at various sites within the gastrointestinal tract.
- E. Development of techniques for the preservation and transplantation of small intestine and pancreas.
- F. Development of non-invasive measures of pancreatic exocrine function.
- G. Development of a test for determining the hepatotoxic potential of drugs, agents or additives that is more sensitive than testing in mice and reflects the human response to the test compound.
- H. Development of animal models to study hepatotoxic agents.
- I. Development of non-invasive techniques to detect liver disease.
- J. Development of non- or minimally-invasive devices/ techniques to measure portal pressure for evaluating portal hypertension in patients with cirrhosis.
- K. Development of an extracorporeal liver assist device to provide temporary therapeutic assistance in cases such as fulminant hepatic failure or drug overdose.
- L. Development of cryopreservation techniques for human hepatocytes that would maximize viability and cell culture growth potential of thawed cells.
- M. Creation of artificial organs or development of effective xenographic techniques for liver transplantation.
- N. Development of molecular standards for Hepatitis B virus quantitation and typing.
- O. Development of an economical, accurate, and fast test for glutes and gliadins in foods.
- P. Development of humanized mouse models of multi-allelic diseases.
- Q. Development of measurements to quantitate phenotypic or metabolic markers of disease progression in animal models, thus reducing the numbers of animals needed.
- R. Identification of surrogate markers looking at the plasma/sera proteome or metabolome at different stages of digestive or liver disease.
- S. Development of novel proteomic or metabolomic technologies designed to study digestive and liver diseases, and their complications.
- T. Development of biomarkers or imaging methods that quantitatively measure hepatic regeneration.
- U. Development of biomarkers that quantitatively assess the degree of cold and warm ischemia injury in donor liver organs.

III. NUTRITION, OBESITY, AND EATING DISORDERS

- A. Development of more accurate methods for assessing overall nutritional status.
- B. Development of a non-invasive breath or blood test to accurately measure dietary intake.
- C. Development of better means to detect food borne pathogens with the goals of (1) preventing their inclusion in foodstuffs and (2) better treatment of acute infections.
- D. Development of safe drugs that inhibit appetite or increase energy expenditure.
- E. Development of computerized interventions for weight-loss/maintenance, prevention of weight gain and/or increasing physical activity.
- F. New technologies for quantitative assessment of body composition.

Kidney, Urologic and Hematologic Diseases

The Division of Kidney, Urologic, and Hematologic Diseases supports research into basic mechanisms of the organ and tissue function, and the diseases of the kidney, urologic and hematologic systems. Projects are expected to help develop an understanding of the physiology, pathophysiology, and related diseases of the kidney, urinary tract, and blood and blood forming systems so that rational treatments, prevention strategies, and/or arrest of diseases may be devised. Support for advances in the technology of cell and molecular biology that will enhance research in kidney, urologic and hematologic diseases is encouraged. Research opportunities of interest to small businesses include, but are not limited to:

I. DEVELOPMENT OF A GENOMIC TOOLBOX FOR STUDY OF KIDNEY, PROSTATE, BLADDER, OR RED CELLS, WHICH WOULD INCLUDE:

- A. Library generation and gene identification from whole organ or rare compartments in normal, developing, or injured tissues.
- B. Antibodies or phage libraries that will facilitate the prospective identification and purification of renal cell types.
- C. Strategies to deal with the anatomical complexity, increase the representation of low abundance transcripts, or decrease the redundant sequencing of over-represented or known genes.
- D. Bioinformatics tools.
- E. Flexible databases useful for designing organ-specific databases and web sites.
- F. Techniques for visualizing RNA distribution within cells or tissues.
- G. New methods to acquire material from archival samples.

II. APPLICATION OF PROTEOMICS AND METABOLOMICS TO KIDNEY, UROLOGIC AND HEMATOLOGIC DISEASES

- A. Identification of surrogate markers in the plasma or serum that correlate with acute or chronic kidney disease, urologic diseases of the prostate or bladder, or dysregulation of iron metabolism or other hematologic diseases (not leukemia), such as hemoglobinopathies or thalassemia.
- B. Identification or development of novel proteomic or metabolomic technologies designed to study kidney, urologic, or hematologic diseases.

III. KIDNEY

- A. Development of antibodies or phage libraries specific for the individual cell types of the kidney.
- B. Development of both data and cell banks of diabetic kidney disease families and autosomal and recessive polycystic disease families for use by the research community.
- C. Development of pharmacological agents that might be used to intervene in acute or chronic renal disorders and in disorders of renal hemodynamics, blood pressure, electrolyte metabolism, and extracellular volume regulation.
- D. Means to improve physiologic homeostasis in maintenance dialysis therapy through the:
 - 1. Improvement of blood access to permit continuous access to the circulation with minimal inflammation.
 - 2. Development of means to provide for continuous anticoagulation.
 - 3. Development of reliable, non-invasive, online hemodialysis monitoring systems assessing real-time treatment parameters such as blood volume, access flow, and urea clearance.
- E. Studies to improve the efficiency of maintenance dialysis:

1. Development of innovative methods to produce more efficient and less morbid forms of renal dialysis (e.g., GI dialysis, artificial kidney).
 2. Studies on biocompatibility of artificial kidney membranes, in surface sensitive proteins, complement, and clotting mechanisms.
 3. Development of new agents for sterilizing dialysis membranes and methods / agents to reduce hemodialysis or peritoneal dialysis catheter-related infections.
 4. Studies on biocompatibility of hemodialysis and peritoneal dialysis catheters to decrease the foreign body response.
- F. Improved techniques of preservation and storage of kidneys intended for transplantation.
- G. Development of material(s) for construction of urinary catheters that may reduce the incidence of infection in the urinary tract, and materials that decrease urethral and bladder inflammation due to foreign body.
- H. Development of improved renal imaging techniques, differential renal function assessments and diagnostic assessment of benign parenchymal diseases.
- I. Development of early diagnostic tools, preventative measures, and treatment modalities for acute kidney injury.
- J. Identification of mediators of kidney injury during sepsis and pharmacological means to block these effects.
- K. Development of new non-invasive methods for measuring kidney function:
1. Reliable, non-invasive, non-radioactive methods of measuring glomerular filtration rate (GFR).
 2. Identification of serum factors released by damaged kidney cells.
 3. Characterization of changes in kidney hormonal function in kidney disease at various stages of severity.
 4. Development of new biomarkers for early detection of kidney dysfunction, prediction of progression, and early indication of recovery.
 5. Development of rapid, accurate, and cost effective means of quantifying urine albumin.

IV. UROLOGY

- A. Analyses of factors responsible for initiation and progression of benign prostatic Hyperplasia (BPH) leading to the development of a diagnostic tool. Development of animal, computer, or in-vitro models for the study of BPH, including culture conditions for *in vitro* culture of cells from benign prostatic hyperplasia.
- B. Development of diagnostic modes to clinically non-invasively or minimal-invasively measure bladder obstruction before and after surgical or pharmaceutical intervention and/ or treatment devices for bladder outlet obstruction.
- C. Prevention, diagnostic, or treatment modalities for urinary tract infections.
- D. Kinetics of renal stone formation, such as characterization of growth and dissolution, or crystal growth inhibition, and definition of reliable biochemical profiles of stone forming patients. Development of diagnostic device for biochemical profiling of stones either in-vitro or in-vivo.
- E. Development of localization methods through imaging or non-invasive methods or instrumentation using minimally-invasive methods to access stones for therapy. Methods to directly improve access to difficult stones.

- F. Development of additional therapeutic agents and methods for prevention and/or treatment of urolithiasis.
- G. Development of more real-time diagnostic assessment of bladder and urinary function using non-invasive, remote or minimally invasive measures, which can include neuro-pharmacological/neuro-physiological assessments in urodynamics.
- H. Objective and diagnostic measurement devices or methods for assessment of urinary voiding and storage disorders, including stress, urge, and mixed incontinence, both in adults and children.
- I. Development of non invasive or minimally invasive treatment methods or pharmacological for urinary incontinence and/or bladder instability.
- J. Non-invasive or minimally invasive methods to diagnosis bladder inflammation or bladder epithelial and/ or bladder wall changes of non-cancerous origin.
- K. Non-invasive, reduced or non-radiological diagnostic methods for evaluating vesico-ureteral reflux in children and infants.
- L. Methods for determining inflammatory cytokines, histamines, or other factors in voided urine, as markers for lower urinary tract inflammatory processes or other urologic disorders, including chronic and acute urologic pain disorders.
- M. Development of simple diagnostic kits for evaluating growth factors in urine in a clinical laboratory.
- N. Development of new or enhanced methods to derive synthetic or semi-synthetic biological matrices or other tools to treat urologic disease and/or augment the functionality of urologic tissues and organs.

V. HEMATOLOGY

- A. Development of methods and equipment for routine high volume isolation of highly purified hematopoietic stem and progenitor populations.
- B. Identification of new methods to assay hematopoietic stem and progenitor cells with short- and long-term repopulation models amenable to serial examination.
- C. Development of chemically defined reagents that support hematopoietic stem cell proliferation and differentiation.
- D. Definition of culture conditions using serum-free medium that will support the ex vivo expansion of hematopoietic stem and progenitor cells.
- E. Development of new approaches for identifying, isolating, and genetically analyzing fetal erythrocytes in the maternal circulation.
- F. Development of novel methods for the delivery of DNA, proteins, and other compounds to hematopoietic stem cells.
- G. Development of rapid, high throughput microarrays for accurate assessment of gene expression profiles of hematopoietic stem cells.
- H. Development of non-invasive systems for monitoring the total hemoglobin and hematocrit, suitable for use with adults or neonates.
- I. Application of nanotechnology to the measurement of blood parameters and diagnosis of blood disorders.
- J. Development of new methods for the non-invasive or minimally invasive measurement of body iron.
- K. Adaptation of MRI technology for the non-invasive measurement of body iron:
 - 1. Develop appropriate MR measurement method(s).

2. Optimize RF coils for the body region of interest (primarily heart, liver, and pancreas).
 3. Develop magnets of the appropriate magnetic field strength(s).
 4. Develop a reliable method for calibrating, validating, and standardizing organ specific iron concentration measurements as detected by magnetic resonance imaging.
 5. Determine the most appropriate magnetic resonance method for determining relaxation times and susceptibility.
 6. Develop indicator materials for direct MR measurement of iron concentration.
- L. Design of therapeutic drugs for inducing fetal hemoglobin synthesis.
- M. Development and validation of a sensitive, specific, reproducible, quantitative, and clinically applicable assay method for measuring serum hepcidin levels, as well as cellular hepcidin and ferroportin expression levels.
- N. Design and validation of novel therapeutic agents that modulate hepcidin and cellular ferroportin expression and/or activity *in vivo*.

Other Research Topic(s) Within the Mission of the Institute

For additional information on research topics, contact:

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NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES (NIEHS)

Human health and human disease result from three interactive elements: the environment, genetics, and age. The mission of the NIEHS is to reduce the burden of human disease and dysfunction from environmental causes by understanding each of these components and how they interrelate. NIEHS achieves its mission through a multidisciplinary biomedical research program, prevention and intervention efforts, and a communication strategy that encompasses training, education, technology transfer and community outreach. NIEHS supports research and training focused on the identification, assessment and mechanism of action of agents in the environment and how they contribute to disease and dysfunction. The ultimate goal of these NIEHS activities is to then transfer this knowledge for the public benefit. The SBIR program uses a combination of research, technology transfer and communication strategies to aid the mission of NIEHS.

For additional information about the areas of interest to NIEHS, visit our home page at <http://www.niehs.nih.gov>.

Tools for Improved Exposure Assessment

Fundamental to the NIEHS mission is the ability to quantify an individual's exposure, as well as the unique characteristics that account for individualized responses to the exposures. The goal for improved exposure assessment is to develop new technology and assays to generate precise measurements of human exposure to chemical and biological agents that may lead to disease or dysfunction. The desired application of these technologies and assays is in population-based (epidemiological) or clinical research and practice. An emphasis is placed on tools that provide individual exposure metrics either at the point of contact or through measuring internal dose of environmental agents.

It is anticipated that the new technologies and assays, such as those based on micro- and nanotechnology and molecular imaging, may provide sensitive, high-throughput, and potentially portable systems capable of measuring exposure to environmental agents and the impact of the exposures on human biology.

1. TECHNOLOGIES FOR GENERATING PRECISE MEASUREMENTS OF INTERNAL DOSE OF ENVIRONMENTAL AGENTS

The NIEHS supports the development of technologies and devices to generate precise measurements of internal dose of individual environmental agents and or their metabolites in real time and over time. It would be especially valuable to analyze multiple agents within a single class or multiple agents across more than one class. The development of a modular design allowing measurement of specific classes of chemical exposures for application in epidemiological studies (e.g., pesticides, endocrine-active chemicals, toxic metals, or components of indoor air pollution) is preferred. Approaches that combine detection of individual analytes together with functional assays, e.g., measures of total estrogenicity or genotoxicity, are also encouraged. Likewise, an emphasis is placed on measuring environmental factors with mixed routes of exposure (i.e., inhalation, ingestion, and dermal exposure) for which biomonitoring is the only comprehensive exposure metric. In addition, NIEHS is interested in the development of economical technologies and approaches for storing human biological samples for long periods for subsequent analyses of analytes or macromolecules. Methods to store dried blood spots, urine samples,

etc. with low cost, minimum storage requirements, and minimal degradation of sample quality are needed.

Examples include but are not limited to:

- A. Development of sensors for measuring the levels of toxicants in biospecimens easily obtained from an individual, such as finger prick of blood, buccal cells, hair, exhaled breath, meconium, or urine.
- B. The development of integrated devices linking exposure at the point of contact, internal dose, and biological response.

2. WEARABLE TECHNOLOGIES FOR PERSONAL EXPOSURE ASSESSMENT AT THE POINT OF CONTACT

The NIEHS is interested in developing and validating new products/devices, tools, and assays to improve our ability to precisely measure an individual's exposure to environmental agents, with high temporal and spatial resolution. Ideally, the technologies, tools and assays will be of appropriate scale to be field deployable and/or wearable. These point-of-contact devices should be capable of measuring simultaneously and in near real time, multiple agents within a single exposure class (e.g., multiple types of metals, multiple size fractions of particulate matter, multiple components of diesel exhaust) and/or multiple agents across more than one exposure class. Exposures of interest include ozone, particulate matter, diesel exhaust, metals (e.g., arsenic, cadmium, or mercury), volatile organic compounds, polybrominated diphenyls (PBDEs), polycyclic aromatic hydrocarbons (PAHs), mold/microbial toxins, allergens and pesticides/herbicides. Examples include but are not limited to:

- A. Novel technologies and assays to generate precise, quantitative measures of human exposure to environmental compounds at the point of contact or in easily obtained biological samples (e.g., skin, breath, saliva, or nasal mucosa). An emphasis is placed on the ability to measure multiple analytes simultaneously.
- B. Remote sensing technologies for detecting, quantifying, and monitoring household exposures to toxicants and/or bioaerosols.
- C. Technologies that can integrate multiple types of exposure, including chemical toxicants together with dietary factors or physical activity, or exposure to toxins produced by pathogenic organisms.

Hazardous Substances Detection and Remediation Program

The NIEHS Superfund Research Program (SRP) is interested in applying innovative approaches to develop novel strategies to characterize, monitor, and remediate hazardous substances at contaminated sites. SRP encourages applicants to develop green / sustainable detection technologies and remediation approaches that improve energy efficiency and reduce waste generation.

Examples include but are not limited to:

- A. Development of advanced technologies that allow for real-time, on-site monitoring such as nanotechnology-based sensors and probes, biosensors, self-contained miniaturized toxicity-screening kits and miniaturized analytical probes and data analysis tools.
- B. Development of methods or devices to detect and measure vapor intrusion or to detect non-aqueous phase liquids (NAPLs) and dense non-aqueous phase liquids (DNAPLs) in the subsurface.
- C. Development of assays or devices to determine the extent to which a contaminant is bioavailable.
- D. Development of instruments to identify subsurface geological structures and hydro-geological configurations and to sample for the presence of contaminants in these structures.
- E. Development of novel technologies for in situ remediation of contaminated sediments, soils, and groundwater.

- F. Development of cost-effective devices to detect or remediate chemical mixtures in environmental media.
- G. Development of nano-enabled structures, electrochemical methods, photocatalytic processes, thermal treatments, or filtration-based methods of remediation.
- H. Development of bioremediation and phytoremediation technologies including the use of genetic engineering approaches.

SRP recognizes the important public health impact of detection or remediation technologies that are applicable to non point-source air pollution and drinking water; however, a higher priority will be placed on remediation and detection technologies with a clear connection to sites impacted by hazardous substances.

Improved Test Systems for Prioritization and Safety Evaluation

The NIEHS is interested in: (1) developing, standardizing, and validating sensitive and specific innovative tests and integrated testing strategies that can reduce, refine, or replace animal use and that will provide improved predictivity, and potential cost and time savings compared to current standard laboratory animal tests (i.e., assays for carcinogenicity, immunotoxicity, reproductive or developmental toxicity, dermal toxicity, and neuro or other organ system toxicity including acute local and systemic toxicity); and (2) developing mid- and high-throughput screens and tests using phylogenetically lower animal species (e.g., insects, fish, worms) to evaluate mechanisms of toxicity to identify mechanisms of chemically-induced biological activity, prioritize chemicals for more extensive toxicological evaluation, and develop more predictive models of *in vivo* biological response. The proposed tests and strategies should use computational and/or biochemical models, cell/ tissue cultures, and/or animal models that are relevant to existing safety assessment databases and human experience, and that can be extrapolated to estimate risks to humans. The endpoints for these tests or assays should take advantage of the new technologies such as genomics, transcriptomics, proteomics, and bioinformatics and of novel endpoints (biomarkers) including those that are non-invasive. Examples include but are not limited to:

- A. Biokinetic models that include the integration of toxicodynamic and biokinetic modeling to predict acute and chronic systemic toxicity from *in vitro* data.
- B. *In vitro* test methods and integrated strategies (e.g., undifferentiated/ differentiated human/mammalian stem cell model systems, organotypic model systems, biochemical activity [e.g., peptide binding]; and computational models) that can be used to prioritize compounds for more extensive testing and/or to predict acute and chronic toxicity by taking into account, for example, metabolism, the ability of chemicals to pass through barriers (i.e., blood brain, kidney, lung, gastrointestinal), and organ specific effects, or which allow the development of endpoints that can be extrapolated to *in vivo* biomarkers of toxicity. An emphasis is placed on the development of engineered 3D tissue systems that include multiple cell types and that replicate the anatomy and function of intact tissue. Of particular interest are systems that replicate key functions of major organs (e.g., skin, kidney, lung and the gastro-intestinal track) and the ability to incorporate immunological function in these models. Also important is the ability of such systems to replicate human xenobiotic metabolism.
- C. Alternative assays and integrated strategies to assess dermal irritation, dermal absorption, dermal hypersensitivity phototoxicity, and ocular toxicity.
- D. Non-mammalian or invertebrate models for specific toxicities that utilize endpoint that are conserved across species so the results can be extrapolated to human risk.
- E. Identification and validation of predictive biomarkers that can be used to obtain improved mechanistic information and/or serve as the basis for earlier endpoints in toxicological studies.
- F. Accelerated throughput methods for the generation of RNA transcriptional and DNA methylome data from animal and/or human formalin fixed, paraffin embedded tissues.

- G. Computational models that use data from *in vivo* and *in vitro* omics studies, *in vitro* mid- and high-throughput assays, and classical animal and human toxicological studies to link chemicals to genes, genes to pathways, and pathways to disease.

Education and Outreach

As part of its Partnerships for Environmental Public Health (PEPH) Program, NIEHS is interested in developing educational and training resources for students of all ages, educators, health care professionals, and the lay community to enhance their knowledge of environmental health sciences and apply it to their daily lives. These resources are an important part of our strategy that encompasses both communication and capacity building through training, education, and community outreach. Resources may be directed to all levels of education: Kindergarten through 12th grade, undergraduate, graduate, adult education, health care professional training, and community outreach. Products may include:

- A. Mobile and distance strategies. With the proliferation of applications for mobile phone use as well as tablet technologies, NIEHS encourages the development of applications and technology to increase knowledge of environmental health topics and to apply that knowledge to daily living.
- B. Gaming approaches. These can include materials for use within or outside the classroom. The goal is to enable players to develop understanding of environmental health concepts actively, at their own pace and ability.
- C. Television shows. Educational shows with accompanying lessons or activities to enable broader use of the show to increase awareness of environmental health issues.

Resources on subjects of particular interest include education on known or emerging environmental toxicants, risk communication, environmental justice, health disparities, cumulative exposures, windows of susceptibility, and gene-environment interactions.

All educational resources must be aligned with state and federal standards. Training materials and activities for health care professionals should include continuing education units. Small businesses should partner with environmental health scientists, educators, communication researchers, health literacy experts, or training specialists to form research teams with the required expertise to develop technology or products using the best available science in environmental health.

Other Topics Within the Mission of the Institute

For additional information on research topics, contact:

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For information on the Hazardous Substances Detection and Remediation Program, contact:

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For express mail:
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Morrisville, NC 27560

NATIONAL EYE INSTITUTE (NEI)

The NEI supports research with respect to eye diseases, visual disorders, mechanisms of normal visual function, preservation of sight, and the special health problems and requirements of individuals with impaired vision. Applications for all areas of vision research are encouraged. Examples that may be of interest to small businesses are provided below, but this list is not meant to be exhaustive.

Limited Amount of Award

For budgetary, administrative, or programmatic reasons, NEI may decrease the length of an award and/or the budget recommended by a review committee, or not fund an application. Generally, NEI does not fund Phase I applications greater than \$250,000 total cost per year for up to 2 years or Phase II applications greater than \$750,000 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

The NEI will accept Phase IIB SBIR Competing Renewal grant applications from Phase II SBIR awardees to continue the process of developing technologies that ultimately require federal regulatory approval or require extraordinary time and effort in the Research and Development phase. Such technologies include, but are not limited to, pharmacologic agents, biological products, and devices. These technologies should be clearly related to the mission of the NEI. This renewal grant should allow small businesses to reach a stage where interest and investment by third parties is more likely. The Competing Renewal application must be a logical extension of a previously completed Phase II (R44) SBIR grant. NEI grantees seeking SBIR Phase IIB Competing Renewal funding must submit an application within a period no later than the first six receipt dates following expiration of the previous Phase II budget period. Budgets not to exceed \$1 million total costs per year and time periods up to two (2) years may be requested for this Phase IIB Competing Renewal opportunity.

Potential applicants are strongly advised to contact Dr. Jerome Wujek (contact information provided below) before beginning the process of putting an application together.

The following topics are meant for illustrative purposes only and are not exclusive of other appropriate activities.

General Research and Development Topics

NEI is interested in providing support for the development of new technologies, strategies, research tools, reagents and methods that can be applied to basic and translational research which will benefit vision health. This encompasses research and development of innovative enabling technologies in areas of genomics, proteomics and nanotechnology. More specific topics include drug and high throughput assays; drug delivery systems; gene therapy, cell-based therapy and regenerative medicine; development of *in vitro* and *in vivo* disease models; surgical devices and materials; telemedicine and health education; and design/fabrication of new or improved ophthalmic instruments for diagnosis and treatment of eye disorders.

Specific Research and Development Topics

Retinal Diseases

New therapeutic approaches for inflammatory and degenerative diseases and for inhibition of abnormal angiogenesis in the retina and choroid; Better methods of diagnosing and treating diabetic retinopathy and other vascular diseases; Non-invasive techniques for early diagnosis of macular degeneration and other retinal degenerative diseases; Instruments and procedures for improved surgical management of retinal detachments; Retinal prostheses to help restore visual function; Better methods for cell or tissue transplantation.

Corneal Diseases

New diagnostic tools, therapeutic agents and drug delivery methods for the treatment of corneal injury, infection, dry eye, ocular pain, and other ocular surface disorders; New biomaterials for corneal prostheses and corneal transplants; Instruments and procedures for correcting the refractive power of the cornea and/or measuring the cornea's optical properties or other physiological properties.

Lens and Cataract

New approaches in the post-operative management of cataract surgery; New surgical instruments for cataract extraction and new biomaterials for replacement of the natural lens; Design/fabrication of accommodative intraocular lenses.

Glaucoma and Optic Neuropathies

New therapeutic agents, instruments, and procedures for the diagnosis and treatment of glaucoma; Non-invasive methods to measure changes in the optic nerve head and retinal fiber layer.

Strabismus, Amblyopia, and Refractive Error

New approaches to detect and treat strabismus, amblyopia, and myopia; New tools and techniques for vision screening; New or improved methods and materials for correcting the refractive power of the eye and/or measuring the eye's optical properties or other physiological properties; New materials and manufacturing processes for eyeglasses and contact lenses.

Visual Impairment and Blindness

Instruments and methods to better specify, measure, and categorize residual visual function; New or improved devices, systems, or programs that meet the rehabilitative and everyday living needs of blind or visually-impaired persons.

Additional Information

The NEI's programs are described in more extensive detail in documents which are available from the Institute. For additional information about the research programs of the NEI, please visit our home page at <http://www.nei.nih.gov>.

For more information on research topics, contact:

Jerome Wujek, Ph.D.
Research Resources Officer
Division of Extramural Research
National Eye Institute
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Bethesda, MD 20892

National Eye Institute
301-451-2020, Fax: 301-496-2297
Email: wujekjer@nei.nih.gov

For administrative and business management questions, contact:

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NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES (NIGMS)

The NIGMS supports research and research training in the basic medical sciences and related natural and behavioral sciences and in specific clinical areas (i.e., clinical pharmacology, trauma and burn injury, sepsis and anesthesiology). The NIGMS also supports health-related research that is otherwise not assigned to another of the PHS components. The four divisions that support research of potential interest to small businesses and their collaborators include:

Division of Cell Biology and Biophysics

Division of Genetics and Developmental Biology

Division of Pharmacology, Physiology, and Biological Chemistry

Division of Biomedical Technology, Bioinformatics, and Computational Biology

For additional information about areas of interest to the NIGMS, please visit our home page at <http://www.nigms.nih.gov>. This site includes staff contact information by program area (<http://www.nigms.nih.gov/About/ContactByArea.htm>). It also includes links to program announcements that highlight NIGMS areas of special emphasis (<http://www.nigms.nih.gov/Research>). In some cases, these announcements specifically mention the SBIR and STTR grant mechanisms, in most cases they do not. However, it is clear that small businesses could make contributions to the research objectives described in these announcements.

Phase IIB Competing Renewal Awards

NIGMS will accept Phase IIB SBIR-only Competing Renewal grant applications to continue the process of developing products that ultimately require 1) clinical evaluation, 2) approval by a Federal regulatory agency, and 3) continuing refinements to durable medical equipment (DME) designs such as cost reduction, testing for safety, durability, and reliability, and meeting or establishing standards. This renewal grant should allow small businesses to get to reach a stage where interest and investment by third parties is more likely. Such products include, but are not limited to biological products, devices, drugs, medical implants, etc. related to the mission of the NIGMS. The previously funded Phase II SBIR grant need not have been submitted in response to a particular solicitation, as long as the research is appropriate to the purpose of this solicitation. Budgets up to \$750,000 total costs per year and time periods up to 2 years may be requested for this Phase IIB Competing Renewal opportunity. These awards are intended to support completion of research needed to obtain an IND or IDE. Applicants must provide evidence that they have consulted formally with the FDA concerning the research needed for the development of a drug, biologic or medical device and that the proposed research will address these regulatory requirements. Such evidence should include FDA correspondence from a pre-IND meeting for an IND application or a pre-IDE meeting for an IDE application, and the status of the project in a timeline related to Federal regulatory approval processes.

Prospective applicants are strongly encouraged to contact NIH staff listed at the end of this NIGMS topics announcement prior to submission of a Phase IIB Competing Renewal application. Prospective applicants are strongly encouraged to submit to the program contact a letter of intent that includes the following information:

- Descriptive title of the proposed research
- Name, address, and telephone number of the Principal Investigator
- Names of other key personnel
- Participating institutions
- Funding Opportunity Announcement Number (e.g., PA-12-XXX)

Division of Cell Biology and Biophysics

Research on membrane synthesis, structure, and function; membrane models; membrane transport; cell division; cell organization; cell motility; and biophysics of proteins, nucleic acids, and biological assemblies, including viral entry, packaging, maturation, and release, as well as the development of instrumentation, components, and methods for the analysis of cellular components and macromolecules by imaging, spectroscopy, and diffraction analysis.

SBIR and STTR applications on the application of cell biology, biophysics, biochemistry, physics, mathematics, and chemistry to biomedical problems, and the development of instrumentation to facilitate research in cell biology and biophysics, such as, but not limited to, the topics listed below are welcome.

- A. Development and improvement of methods for the expression, solubilization, and purification of milligram quantities of regulatory, cellular, and membrane associated proteins, as well as for the preparation of specifically labeled macromolecules and the recovery of proteins from inclusion bodies.
- B. Development of novel ligands, inhibitors, and other probes for spectroscopic and microscopic analysis of cellular assemblies and viral structures, macromolecules and components, their localization and function *in vivo* and at a single molecule level.
- C. Development of instrumentation, devices, and methods for detecting in real time, analyzing, and separating biologically important compounds, macromolecules, and their interactions.

- D. Development of new methods and materials directed toward the solution of biological macromolecule structures, including membrane proteins, assemblies and complexes by, but not limited to, x-ray diffraction, electron diffraction, NMR and mass spectroscopy.
- E. Imaging probes and sensors, other reagents and methods, instrumentation, software for microscopy, spectroscopy, and single molecule analysis of molecules, cells, tissues, embryos and small model organisms. Technologies for applications of microscopy, spectroscopy and single molecule analysis in basic biomedical research, including but not limited to light, electron, X-ray and scanning probe microscopy and fluorescence, magnetic and electron paramagnetic spectroscopy. NOT included are small animal and preclinical imaging and high throughput platforms for diagnostic and clinical applications.
- F. Computational methods for analysis, prediction, and improving methods for determination of macromolecular structures and structure-function relationships.
- G. Development of computerized tools that might be used in the presentation of the concepts of cell and structural biology to audiences at a variety of levels.

Division of Genetics and Developmental Biology

Research on developing a better understanding of fundamental processes and mechanisms of development and inheritance in health and disease. Support of basic topics in genetics and developmental biology, including nucleic acid chemistry, the structure of genetic material, the mechanisms of transmission and expression of genetic information, cellular regulation of growth and differentiation, and population genetics. Areas that may be of interest to small businesses include, but are not limited to:

- A. Development of computer software for the analysis of the primary and secondary structures of nucleic acids as these relate to genetic problems.
- B. Improvement in procedures for the separation and analysis of nucleic acids and proteins as these relate to genetic problems.
- C. Improvement of methodology (technology) for genetic analysis (e.g., gene expression, probes).
- D. Development of probes for detection of human genetic polymorphisms, including disease genes.
- E. Development of improved procedures for cytogenetics and diagnostic array technology.
- F. Improvement in procedures (statistical, computational, laboratory) for the analysis of gene flow and gene dynamics in human populations.
- G. Development of improved vectors for gene transfer.
- H. Development of valid animal models for genetic diseases and birth defects.
- I. Development of quantitative approaches to the analysis of complex biological systems.
- J. Development of tools and technologies to detect and monitor complex human phenotypes or traits.
- K. Development of technology to derive and expand pluripotent cell populations from non-embryonic sources, for example, induced pluripotent stem cells (iPS).
- L. Development of improved technology to scale up the growth of induced pluripotent stem cells in culture and to regulate their differentiation state
- M. Development of markers, reagents and tools to characterize the unique properties of iPS cell lines and to distinguish them from adult stem cells and more differentiated cells.
- N. Development of existing human embryonic stem cell lines and new or existing iPS cells as a model system for drug discovery.

- O. Development or improvement of methodology for generation of antibodies or other affinity reagents for proteins and other small molecules in non-mammalian genetic model systems.
- P. Improvement in procedures (statistical, computational, laboratory) for the high- and medium-throughput analysis of gene expression patterns and regulatory networks.
- Q. Development or improvement of methods for high throughput detection of epigenomic changes.
- R. Development or improvement of methods for characterizing the metabolic interactions of complex communities of microorganisms particularly those involved in host-microbe interactions.
- S. Development of improved or novel methodology for structure/function analysis of very large macromolecular complexes involved in transmission or expression of genetic material.

Division of Pharmacology, Physiology, and Biological Chemistry

Research related to the actions of therapeutics, including anesthetics, and the development of biotechnological methods for their production and investigation. Research on cell signaling molecules and signaling intermediates, particularly those related to G-protein coupled receptors. Research in the field of glycomics, especially tool and methods development for this emerging field. Research on pain management as it relates to anesthesia and the perioperative period. Research on responses to traumatic injury, including burn injury, and methods to mitigate these responses. Research on wound healing and tissue repair. Research on the causes and treatments for common complications of critically ill patients (sepsis, systemic inflammatory response syndrome, multiple organ failure), especially directed towards the role of the inflammatory and innate immune responses. Research leading to new knowledge of physiological functions at the molecular, cellular, and organ systems levels. Research on the structure, function, and biosynthesis of cellular components and cellular metabolism, bioenergetics, and mechanisms of enzyme action, regulation, and inhibition. Research leading to the synthesis of new chemical entities or development of new chemical methods to probe biological phenomena or to alter the behavior of biological systems. Examples include, but are not limited to:

- A. Methods for isolation, characterization, and production of natural and bio-engineered products.
- B. Development of synthetic methodology to improve the efficiency (broadly defined) of discovery and production of bio-medically relevant compounds.
- C. Development of enzymes, catalytic antibodies, ribozymes, artificial enzymes, and host molecules as drugs or synthetic tools.
- D. Isolation, characterization, and development of factors and strategies, methods, or treatments involved in tissue repair and wound healing. Development of artificial skin and skin replacements.
- E. Improved systems for collection, processing, and analysis of real time physiological data from injured or critically ill patients. Application of systems biology or complexity theory approaches towards understanding the physiology of injured and critically ill organisms. Development of tools, software, algorithms, etc. needed to link clinical, demographic, physiological, genomic, proteomic or other datasets of injured or critically ill organisms.
- F. Metabolomics/metabonomics of injury and/or critical illness.
- G. Development of strategies, methods, or new technologies to improve the delivery, monitoring, safety and efficacy of anesthesia.
- H. Research to improve drug design and delivery.
- I. Research to improve drug bioavailability by improved understanding of factors that influence absorption, metabolism, transport, or clearance of therapeutics and underlying mechanisms. Application of pharmacokinetic and pharmaceutical principles to the study of large biomolecules, such as proteins, polypeptides, and oligonucleotides.

- J. Research to discover, detect, and understand the genetic basis of individual differences in drug responses (pharmacogenomics).
- K. Development of novel *in vivo* and *in vitro* methods to predict the safety and toxicities of pharmacologic agents.
- L. Development of bioinformatic, mathematical, and/or computational approaches/resources and/or pharmacokinetic modeling programs which utilize ADME parameters of drugs and pharmacogenomic information of individual patients or patient populations to reduce adverse drug reactions in individual patients.
- M. Development of ontologies and modules useful for combining and mining databases containing genotype and phenotype information in order to discover correlations for drug effects, either therapeutic or adverse.
- N. Development of methods and tools for the field of glycomics including but not limited to development of: specific glycan structural databases, methodologies for synthesis of robust glycan libraries, glycan labeling reagents and glycol-enzyme inhibitors, analytical tools for determining carbohydrate structure and assessing its biological function.
- O. Development and application of methods and materials for the elucidation of membrane protein structures at or near atomic resolution.
- P. Development of high-throughput methods for sequencing and re-sequencing of mitochondrial genes and relevant nuclear genes and for proteomic and/or functional profiling of mitochondria in diagnosis of mitochondrial diseases.
- Q. Development of new metal ion chelators and other tools to probe and/or alter the localization and concentration of metal ions in cells and in whole organisms. Research to exploit metal metabolism and metal-regulated cellular control and cell-cell signaling processes to probe and/or alter cell function. Research to develop investigational and therapeutic applications of metal-complexes and to understand the factors governing their pharmacology and toxicology.
- R. Development of high-throughput methods and strategies to characterize the function of proteins and enzymes and/or define the functional interrelationships of proteins and enzymes.
- S. Development of research tools to promote scientific collaboration in any of the above areas of research. For example, applications software for secure peer-to-peer networking to facilitate the exchange of scientific data and research materials or to construct a searchable distributed database.
- T. Development of tools to characterize oxidative stress and oxidative stress related molecules (NO, peroxynitrite, hydrogen peroxide, lipoxidation products modified proteins, DNA modifications, etc.) including the extent and/or localization (by organ/tissue/cell/organelle) of oxidative stress.

Division of Biomedical Technology, Bioinformatics, and Computational Biology

New or improved instruments, devices, and related methodologies to facilitate biomedical or behavioral research. Instrumentation includes, but is not limited to mass spectrometry, nuclear magnetic resonance, optical or laser spectroscopies, X-ray absorption/diffraction/scattering, detectors, electron or confocal microscopies, electrophoresis and other separation techniques, bioreactors, centrifugation, and flow cytometry. New or innovative tools and methods in bioinformatics and computational biology, including social sciences/social, population, and behavioral modeling research.

- A. ***Bioinformatics and Computational Biology***: Development of information and communication technology for computer and other mathematical sciences in support of biomedical or behavioral research, including:
 1. Development of tools and methods to model complex biological systems.
 2. Development of tools and methods for behavioral and social modeling.

3. Development and enhancement of databases and data formats for activities.
 4. Development of tools and methods for scientific visualization, data mining, and integration and interoperability of different databases and varying modalities of data.
 5. Design and development of software and hardware for improving the effectiveness of computational approaches in biomedical research.
 6. Development of computational biology software packages for integrative analysis of genomics data, especially ones relevant to applications of new sequencing technologies. The proposed work should apply best practices and proven methods for software design, construction, and implementation to promote adoption by a broad biomedical research community.
- B. **Technology for Systems Biology:** Development of novel technologies for proteomics, glycomics, metabolomics, and other aspects of systems biology for discovery and clinical applications, (e.g., sample handling, separations, mass spectrometry, and computational tools for protein identification, data curation and mining).
- C. **Technology for Structural Biology:** Development of detectors and cameras for studying the structures of biomolecules in the size range of peptides to cells, using synchrotron radiation and multiple types of microscopy.

Other Research Topic(s) Within the Mission of the Institute

For additional information on research topics, contact:

Cell Biology and Biophysics

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Pharmacology, Physiology, and Biological Chemistry

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NATIONAL HEART, LUNG, AND BLOOD INSTITUTE (NHLBI)

The NHLBI plans, conducts and supports research, clinical trials and demonstration and education projects related to the causes, prevention, diagnosis, and treatment of heart, blood vessel, lung, and blood diseases and sleep disorders. It also supports research on the clinical use of blood and all aspects of the management and safety of blood resources. The NHLBI SBIR/STTR program fosters basic, applied, and clinical research on all product and service development related to the mission of the NHLBI. The NHLBI has three extramural program divisions, described below.

Cardiovascular Sciences

The Division of Cardiovascular Sciences (DCVS) supports basic, clinical, population, and health services research on the causes, prevention, and treatment of cardiovascular diseases. The research programs of the Division encompass investigator-initiated research, targeted research, Institute-initiated research in targeted areas of research need and scientific opportunity, specialized centers of research focused on selected research topics, and clinical trials. Research supported by the Division is concerned with the etiology, pathogenesis, prevention, diagnosis, and treatment of coronary artery disease and atherothrombosis; structural heart disease; heart failure and arrhythmias; and hypertension and vascular diseases. A broad array of epidemiological studies is supported by the DCVS to describe disease and risk factor patterns in populations and to identify risk factors for disease. Also supported are clinical trials of interventions to prevent and treat disease; studies of genetic, behavioral, sociocultural, and environmental influences on disease risk and outcomes; and studies of the application of prevention and treatment strategies to determine how to improve clinical care and public health.

Lung Diseases

The Division of Lung Diseases (DLD) supports research on the causes, diagnosis, prevention, and treatment of lung diseases and sleep disorders. Research is funded through investigator-initiated and Institute-initiated grant programs and through contract programs in areas including asthma, bronchopulmonary dysplasia, chronic obstructive pulmonary disease, cystic fibrosis, respiratory neurobiology, sleep-disordered breathing, critical care and acute lung injury, developmental biology and pediatric pulmonary diseases, immunologic and fibrotic pulmonary disease, rare lung disorders, pulmonary vascular disease, and pulmonary complications of AIDS and tuberculosis.

Blood Diseases and Resources

The Division of Blood Diseases and Resources (DBDR) supports research on the causes, prevention, and treatment of nonmalignant blood diseases, including anemias, sickle cell disease, and thalassemia; premalignant processes such as myelodysplasia and myeloproliferative disorders; hemophilia and other abnormalities of hemostasis and thrombosis; and immune dysfunction. Research supported by the Division encompasses a broad spectrum of topics ranging from basic biology to medical management of blood diseases. The Division has a major responsibility for research to improve the adequacy and safety of the nation's blood supply. It also plays a leading role in transfusion medicine and blood banking, including research to evaluate blood donation screening, manufacturing, and processing technologies. The Division also has a major responsibility supporting research in hematopoiesis and stem cell biology and disease. It also supports hematopoietic stem cell transplantation research, and the application of stem cell biology findings to the development of new cell-based therapies to repair and regenerate human tissues and organs.

The NHLBI encourages applications through this omnibus solicitation proposing innovative technologies related to any area within the NHLBI mission.

For more specific information about areas of interest to the NHLBI and a link to the NHLBI Strategic Plan, please visit our home page at <http://www.nhlbi.nih.gov>. In addition you can contact Dr. Kurt Marek (301-443-8778 or kurt.marek@nih.gov) or the Division contact associated with your technology area listed at the end of the NHLBI section.

NHLBI-Supported Funding Opportunity Announcements (FOAs)

These FOAs are listed to inform potential applicants about other funding opportunities to which they can apply; applications submitted in response to this omnibus FOA are not limited to research and development areas described in the following targeted FOAs. The NHLBI encourages mission-aligned applications for innovative technologies outside these targeted areas.

(Funding Opportunity Announcements can be released or expire at any time throughout the year; please refer to the NHLBI SBIR/STTR web site [<http://www.nhlbi.nih.gov/funding/sbir/index.htm>] for active announcements supported by NHLBI.)

1. Virtual Reality Technologies for Research and Education in Obesity and Diabetes (SBIR/STTR): <http://grants.nih.gov/grants/guide/rfa-files/RFA-HL-12-020.html>
2. New Approaches to Arrhythmia Detection and Treatment (SBIR/STTR): <http://grants.nih.gov/grants/guide/pa-files/PA-10-117.html>
3. Directed Stem Cell Differentiation for Cell-Based Therapies for Heart, Lung, and Blood Diseases (SBIR/STTR): <http://grants.nih.gov/grants/guide/pa-files/PA-09-249.html>
4. New Technology for Proteomics and Glycomics (SBIR/STTR): <http://grants.nih.gov/grants/guide/pa-files/PA-11-214.html>
5. Bioengineering Nanotechnology Initiative (SBIR/STTR): <http://grants.nih.gov/grants/guide/pa-files/PA-10-150.html>
6. Innovations in Biomedical Computational Science and Technology Initiative (SBIR/STTR): <http://grants.nih.gov/grants/guide/pa-files/PAR-09-220.html>
7. SHIFT Award: Small Businesses Helping Investigators to Fuel the Translation of Scientific Discoveries (SBIR): <http://grants.nih.gov/grants/guide/pa-files/PA-10-122.html>

Limited Amount of Award

For budgetary, administrative, or programmatic reasons, the NHLBI may not fund an application or may decrease the length of an award and/or the budget recommended by a review committee. Generally, the NHLBI does not fund Phase I applications greater than \$300,000 total costs or project periods greater than 2 years. In addition, the NHLBI does not generally fund Phase II applications greater than \$2,000,000 total costs or project periods greater than 3 years. Applicants considering a requested budget greater than these limits are strongly encouraged to contact program staff before submitting an application.

The NHLBI is interested in tracking the progress of the small business concerns it funds 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 also their growth as a small business concern towards independence from the SBIR/STTR program.

Phase IIB Competing Renewal Awards

The NHLBI will not be participating in the Phase IIB Competing Renewal program through this omnibus FOA; however, the NHLBI will offer Phase IIB Competing Renewal opportunities that focus on the commercialization of SBIR-developed technologies requiring regulatory approval. Applicants are encouraged to contact Kurt Marek, Ph.D., at 301-443-8778 or kurt.marek@nih.gov for additional information.

Additional Programs and Services for NHLBI SBIR Awardees

The NHLBI encourages all Phase II applicants to apply to the NIH [Commercialization Assistance Program](#) to gain assistance in transferring their products to the marketplace.

For additional information on research areas, please contact:

Cardiovascular Sciences

Albert Lee, Ph.D.
Division of Cardiovascular Sciences
Advanced Technologies and Surgery Branch
6701 Rockledge Drive, Room 8204
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301-435-0567, Fax: 301-480-1454
Email: alee@nih.gov

Lung Diseases and Sleep Disorders

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6701 Rockledge Drive
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301-435-0202, Fax: 301-480-3557
Email: ar31t@nih.gov

Blood Diseases and Resources

Phyllis Mitchell
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Transfusion Medicine and Cellular Therapeutics Branch
6701 Rockledge Drive, Room 9148
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301-435-0481, Fax: 301-480-0867
Email: pm154p@nih.gov

Contact regarding transfusion medicine and cellular therapeutics, and blood diseases

Susan Pucie
Division of Blood Diseases and Blood Resources
6701 Rockledge Drive, Room 9138
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301-435-0079, Fax: 301-480-0867
Email: sp34j@nih.gov

Contact regarding hemostasis and thrombosis

NATIONAL HUMAN GENOME RESEARCH INSTITUTE (NHGRI)

The National Human Genome Research Institute (NHGRI) has been guided, since the inception of the Human Genome Project in 1990, by a sequential series of plans, each of which has been developed with considerable input from the scientific community. These plans have always laid out ambitious goals and measurable objectives to gauge progress. NHGRI initiated its most recent planning process in 2008 and concluded with the publication in February 2011 of its newest strategic plan, *Charting a Course for Genomic Medicine from Base Pairs to Bedside* (Nature, 10 February 2011; Volume 470). The phenomenal advances that have marked genomics and have allowed genomic applications to transform many important fields made it an opportune time for the Institute to take a new look at genomics and its future.

The purpose of this document is to provide information to investigators about the breadth of NHGRI's research interests as laid out in the 2011 strategic plan. When appropriate, NHGRI will publish Requests for Applications that will be used to stimulate research in specific areas, to fill gaps in research knowledge, or to generate community resources that will further the mission of genomics or ELSI research.

The following are areas of high interest for investigator-initiated applications; they are not listed in priority order.

Technology and Methods Development

Technology development in DNA sequencing and genotyping are examples of activities that have changed the nature of what scientific research questions are practical to address, have enabled new approaches, and have potentiated the development of new community resource data sets. Many areas of critical importance to the realization of the genomics-based vision for biomedical research require continued technological and methodological developments before pilots and then large-scale approaches can be attempted. Accordingly, the NHGRI will continue to support the development of new, fundamental technologies in all areas of genomics. Important areas in which technology development applications would be responsive to this Program Announcement include (but are not limited to) analyses of gene expression, discovery and characterization of genetic variation; identification of the genetic contributions to health, disease, and drug response; statistical analytic methods for understanding human genomic variation and its relationship to health and disease; and chemical genomics. There is also continued interest in supporting technology development for the comprehensive discovery of functional elements in the human and model organism genomes, and new DNA sequencing technology. Many of these assays would benefit from the ability to work with very small amounts of starting material, to the limit of single cells. As these technologies mature, emphasis should be on high throughput, cost-effective methods that consistently produce very high quality data.

The Institute is also interested in contributing selectively to the development of new and needed technology in related areas, such as proteomics and systems biology research, when NHGRI funding can be used to further a truly unique development that will have a significant impact on the field.

Bioinformatics

Genome databases are essential resources for the biological and biomedical research communities. The creation and maintenance of effective databases are as important a component of research funding as data generation. The NHGRI has been a primary source of support for several major genetics/genomics-oriented databases and will continue to foster technology improvements to develop effective methods for integrating, displaying, and providing access to genomic information. Projects addressing new database technologies to improve the utility of genome databases would be appropriate as applications.

Computational Biology

The NHGRI has supported the generation of many large-scale genomic data sets such as genome sequence, haplotype maps, transcriptome measurements, protein interactions, and functional elements. NHGRI encourages the development of new computational methods and tools to analyze these and other large datasets, and to extract useful biological information from them. Where possible, existing community data standards and methods for data exchange should be used in the development of these new methods and tools. Further information on programs related to genomic databases and computational biology is available at this web site: <http://www.genome.gov/10001735>.

The development of new sequencing technologies has dramatically increased the amount of data produced for genomics. NHGRI is interested in supporting new computational applications for the production and analysis of data from these new sequencing platforms. These applications would include better computational methods for storage, compression and transfer of large datasets by biomedical researchers along with better analysis methods to interpret these data and integrate with other data types. Methods that are fast and computationally efficient are highly desirable.

Some genomic data analysis and display tools have been developed that already are used in the community that would benefit from additional work to support broader dissemination, for example making them efficient, reliable, robust, well-documented, and well-supported. NHGRI will support projects to extend the support for these informatics tools to make them readily adopted by any biomedical research laboratory that wishes to use genomic technologies to address biological questions.

Population Genomics

This is an emerging discipline that applies genomic technologies, such as genome-wide association testing and sequencing, to population studies to identify gene regions, genes, or variants affecting common etiologically complex conditions and predict individual risk. It also investigates the value of applying genomic methods in clinical care for the diagnosis, treatment, and prevention of complex diseases. The research scope of Population Genomics at NHGRI includes: developing resources and statistical methods for observational studies and clinical trials incorporating advanced genomic technologies; conducting proof-of-principle studies that apply genomic technologies to particular conditions that can be generalized to a broader range of conditions (e.g., translating genomic information to clinical care); and developing research methods and infrastructure needed for future epidemiologic studies of genetic and environmental contribution to disease in the United States, including a large, prospective cohort study of genes and environment. For additional information about Population Genomics within NHGRI, please visit this web site: <http://www.genome.gov/19518660>.

Ethical, Legal and Social Implications

NHGRI, through the ELSI Research Program supports research studies that examine issues and, where appropriate, develop policy options regarding the ethical, legal and social implications of genomics. These studies may focus on issues associated with genomic research, genomic medicine or broader societal effects of genomic information and technologies. More detailed information on specific ELSI research priorities within each of these broad areas is available on the ELSI Research priorities web site: <http://www.genome.gov/27543732>.

Other Research Topic(s) Within the Mission of the Institute

Individuals interested in any of the above listed areas are encouraged to contact the NHGRI staff listed below. For more specific information about areas of interest to the NHGRI, please visit our home page at <http://www.genome.gov/Grants/>.

NATIONAL INSTITUTE OF MENTAL HEALTH (NIMH)

The mission of the National Institute of Mental Health (NIMH) is to transform the understanding and treatment of mental illnesses through basic and clinical research, paving the way for prevention, recovery, and cure. Mental disorders constitute an immense burden on the U.S. population, with major depression now the leading cause of disability in the U.S., and schizophrenia, bipolar disorder, and obsessive-compulsive disorder ranked among the ten leading causes of disability. NIMH also takes a leading role in understanding the impact of behavior on HIV transmission and pathogenesis, and in developing effective behavioral preventive interventions. The NIMH conducts a wide range of research, research training, research capacity development, as well as public information outreach and dissemination to fulfill its mission.

For the Institute to continue fulfilling this vital public health mission, it must foster innovative thinking and ensure that a full array of novel scientific perspectives are used to further discovery in the evolving science of brain, behavior, and experience. In this way, breakthroughs in science can become breakthroughs for all people with mental illnesses.

The NIMH SBIR/STTR programs support small businesses to develop technologies that can advance the mission of the Institute, including in basic neuroscience research relevant to mental disorders, translational and clinical research of mental disorders, clinical diagnosis or treatment of mental disorders, and dissemination of evidence-based mental health care. The NIMH Strategic Plan (<http://www.nimh.nih.gov/about/strategic-planning-reports/index.shtml>) and the National Advisory Mental Health Council's workgroup report "From Discovery to Cure" (<http://www.nimh.nih.gov/about/advisory-boards-and-groups/namhc/reports/fromdiscoverytocure.pdf>) present key scientific priorities across these domains, and describe the need for tools to realize these priorities. Research priorities for the NIMH further include aspects of HIV/AIDS prevention, treatment, and care, in accordance with the Trans-NIH Plan for HIV-Related Research (<http://www.oar.nih.gov/strategicplan/>).

For additional information about areas of interest to the NIMH, please visit our home page at <http://www.nimh.nih.gov>.

Also visit the NIMH SBIR/STTR home page: <http://www.nimh.nih.gov/research-funding/small-business/index.shtml>.

Important notes: 1) It is very helpful for potential SBIR/STTR applicants to contact NIMH prior to submitting an application, to ensure the application is of priority/interest to NIMH. Please see the contacts section.

2) An additional criteria that the federal government considers in supporting a small business with SBIR funds, is past commercialization performance. It is expected that small businesses who have received previous SBIR grants, have had success in commercializing their previously supported technologies. Small businesses that are mostly interested in research and development (and not commercialization) should consider other grant mechanisms at NIH, rather than the SBIR program. Program staff at NIMH can help identify the most appropriate grant mechanism to use.

NIMH-Supported Program Announcements:

(Funding Opportunity Announcements can be released or expire at any time throughout the year. See <http://www.nimh.nih.gov/research-funding/small-business/small-business-program-announcements-issued-by-nimh.shtml> for the most up-to-date list of active funding opportunity announcements that NIMH is participating in.)

1. Lab to Marketplace: Tools for Brain and Behavioral Research (SBIR)
<http://grants.nih.gov/grants/guide/pa-files/PA-11-134.html>

2. Competing Renewal Awards of SBIR Phase II Grants for Brain and Behavior Tools (SBIR)
<http://grants.nih.gov/grants/guide/pa-files/PA-11-135.html>
3. Complex Technologies and Therapeutics Development for Mental Health Research and Practice (SBIR)
<http://grants.nih.gov/grants/guide/pa-files/PA-11-113.html>
4. Bioengineering Nanotechnology Initiative (SBIR)
<http://grants.nih.gov/grants/guide/pa-files/PA-10-150.html>
5. Novel Tools for Investigating Brain-derived GPCRs in Mental Health Research (SBIR)
<http://grants.nih.gov/grants/guide/pa-files/PA-10-081.html>
6. NIMH Small Business Innovation Research (SBIR, R44) Notice: Major Programmatic Priorities
<http://grants.nih.gov/grants/guide/notice-files/NOT-MH-11-015.html>
7. Innovative Neuroscience K-12 Education (SBIR)
<http://grants.nih.gov/grants/guide/pa-files/PAR-10-154.html>.

Phase IIB Competing Renewal Awards

See <http://www.nimh.nih.gov/research-funding/small-business/sbir-phase-iib-awards.shtml>. The NIMH will accept Phase IIB SBIR Competing Renewal grant applications in two categories: 1) to continue research and development of technologies that ultimately require federal regulatory approval, and 2) to continue research and development of complex instrumentation, clinical research tools, or behavioral interventions and treatments.

Technologies in the former category (those that ultimately require federal regulatory approval) include, but are not limited to: pharmacologic agents and drugs, biological products, medical devices, vaccines, etc., related to the mission of the NIMH. Phase IIB SBIR Competing Renewal grants for such technologies should allow small businesses to get research and development to a stage where interest and investment by third parties is more likely. Companies engaging in drug development for the treatment of mental health disorders may be eligible to submit Competing Renewal applications through the specific funding opportunity announcement PA-11-133 entitled "Complex Technologies and Therapeutics Development for Mental Health Research and Practice (R43/R44)" <http://grants.nih.gov/grants/guide/pa-files/PA-11-133.html>. For this specific opportunity, budgets up to \$1.0 million total costs per year and time periods up to three years may be requested.

Companies that are developing technologies that do not focus on drug development, but that require federal regulatory approval prior to commercialization, may be eligible to submit a Phase IIB Competing Renewal application through the Omnibus SBIR funding opportunity announcement. For this opportunity, budget limits of up to \$800,000 total costs per year and time periods up to 3 years may be requested.

The following examples would make appropriate topics for proposed NIMH SBIR Phase IIB Competing Renewal projects. These are meant for illustrative purposes only and are not exclusive of other appropriate activities:

- Preclinical studies, including pharmacology and toxicology, beyond those conducted under the Phase I (R43) and initial Phase II (R44) grants. Some *in vivo* or *in vitro* studies would be expected to have been carried out in Phase I or the initial Phase II grant.
- Completion of studies as required by the Food and Drug Administration (FDA) for Investigational New Drug (IND) or Radioactive Drug Research Committee (RDRC) application.
- Studies in normal healthy volunteers to determine a drug's safety profile, metabolism, etc.
- Clinical studies in patient/disease population to assess the drug's effectiveness.

- Assessment of devices with regard to performance standards related to the FDA approval process.
- Safety and effectiveness studies of novel medical devices.
- Evaluation of novel imaging approaches for diagnostic purposes.
- Clinical studies in support of Pre-Market Approval for biomarkers/medical devices by the FDA.

Although technologies in the latter category listed above (complex instrumentation, clinical research tools, or behavioral interventions/treatments) may not require federal regulatory approval, extraordinary time and effort is needed for their research and development. Therefore, NIMH supports Phase IIB Competing Renewal awards of existing Phase II grants for such technologies. The Phase IIB Competing Renewal award for these would provide up to an additional three years of support at total cost funding levels of up to \$800,000 per year.

Please contact the Program Director in the appropriate Division or Dr. Margaret Grabb (listed below) before beginning the process of putting an application together. In addition, prospective applicants are encouraged to submit to the program contact a letter of intent that includes the following information:

- Descriptive title of the proposed research
- Name, address, and telephone number of the Principal Investigator
- Names of other key personnel
- Participating institutions
- Funding Opportunity Announcement (e.g. PA-11-135).

Although a letter of intent is not required, is not binding, and does not enter into the review of a subsequent application, the information that it contains allows NIH staff to estimate the potential review workload and plan the review. It is expected that only a portion of NIMH SBIR Phase II awards will be eligible for a Phase IIB Competing Renewal grant.

Division of Neuroscience and Basic Behavioral Science (DNBBS)

The Division of Neuroscience and Basic Behavioral Science provides support for research programs in the areas of basic neuroscience, genetics, basic behavioral science, research training, resource development, technology development, drug discovery, and research dissemination. The Division has the responsibility, in cooperation with other components of the Institute and the research community, for ensuring that relevant basic science knowledge is generated and then harvested to create improved diagnosis, treatment, and prevention of mental and behavioral disorders.

In this Division, the SBIR and STTR programs support research and the development of tools related to basic brain and behavioral science, genetics, and drug discovery and development relevant to the mission of the NIMH. Such tools include: software (such as informatics tools and resources and tools for analyzing data); hardware (such as the development of instrumentation or devices); wetware (such as the use of iRNAs or other bioactive agents as research tools or molecular imaging agents or genetic approaches to label neural circuits or modify circuit functions); and drug discovery related technologies such as high throughput screening (HTS) or computational pharmacology approaches.

Areas of Emphasis

- Novel imaging probes to study brain structure and function at all levels, from the molecular to the whole organ, using any imaging modality (PET, fMRI, optical, etc.).
- Drug discovery/drug development of novel compounds which act on molecular pathways (receptors, enzymes, second messengers, etc.) that are not typically targeted with currently

available psychiatric drugs, and that have a strong biological justification as a novel mechanism for treatment of psychiatric disorders.

- Novel screening assays for high throughput acquisition and analysis of data about behavior and the brain, from the level of genes to the level of behavior.
- Educational tools aimed at teaching neuroscience concepts, and/or the biological basis of mental disorders to students of all ages.
- Novel technologies that would enable researchers to study how populations of neural cells work together within and between brain regions, in order to understand how changes in neural activity contributes to mental disorders.

Prospective applicants are strongly encouraged to contact Dr. Margaret Grabb (listed below) with questions about the relevance of their interests to the mission of this division.

The Division of Developmental Translational Research (DDTR)

The Division of Developmental Translational Research supports programs of research and research training with the ultimate goal of preventing and curing mental disorders that originate in childhood and adolescence. Relevant disorders include mood disorders, anxiety, schizophrenia, autism, ADHD, conduct disorder, eating disorders, obsessive compulsive disorder, and Tourette syndrome. The division stimulates and promotes an integrated program of research across basic behavioral/psychological processes, environmental processes, brain development, genetics, developmental psychopathology and therapeutic interventions. The mission of DDTR is to translate knowledge from basic science to discover the developmental origins of mental disorders and effect their prevention and cure.

In this Division, the SBIR and STTR programs support research and the development of technologies that can accomplish these goals in pediatric populations.

Areas of High Priority:

- Develop, test and validate reliable and stable biomarkers that can identify at-risk individuals prior to disease onset, improve diagnosis, predict treatment response, or measure disease progression. Biomarkers are also needed in clinical trials to identify dose ranges, to identify a specific subpopulation of subjects to enroll in a treatment trial, or to measure efficacy or toxicity/side effects.
- Develop novel and targeted interventions (pharmacological, cognitive, behavioral, or device-based) that affect particular neural circuits and signaling pathways relevant to the developmental trajectory of the disease.
- Based on expanded knowledge of neurobehavioral trajectories, develop novel objective assessment tools that can identify early signs of risk or onset of recurrence of particular mental disorders or in domains of functioning (see MH's RDoC project: <http://www.nimh.nih.gov/research-funding/rdoc/index.shtml>) for pediatric populations.
- Develop computational behavioral assessment tools that can be used across ages, species, and cultures to evaluate dysfunction in domains relevant to mental disorders (e.g., mood dysregulation, deficits in executive function).
- Develop computational platforms to enable the integration and sharing of data characterizing typical and atypical developmental trajectories in humans and non-human animals.

Prospective applicants are strongly encouraged to contact Dr. Margaret Grabb (listed below) with questions about the relevance of their interests to the mission of this division.

Division of Adult Translational Research and Treatment Development (DATR)

The Division of Adult Translational Research and Treatment Development plans, supports, and administers programs of research, research training, and resource development aimed at understanding the pathophysiology of mental illness and hastening the translation of behavioral science and neuroscience advances into innovations in clinical care. The Division supports a broad research portfolio, which includes studies of the phenotypic characterization and risk factors for major psychiatric disorders; clinical neuroscience to elucidate etiology and pathophysiology of these disorders; and psychosocial, psychopharmacologic, and somatic treatment development. In addition, the Division supports an integrated program to clarify the psychopathology and underlying pathophysiology of psychiatric disorders of late life and to develop new treatments for these disorders.

In this Division, the SBIR and STTR Programs support research aimed at facilitating the validation and commercialization of new methods of assessing psychopathology and measuring treatment response to therapeutic agents. In addition, the SBIR and STTR Programs support the clinical development of novel pharmacologic treatments and technology development used to deliver novel psychosocial approaches to the treatment of mental illness in adults.

Areas of Emphasis

- Conduct early stage, proof of concept clinical trials to advance the development of novel therapeutics. The clinical trials are expected to include biological/behavioral data to assess target engagement and to help determine potential success or failure of the compound before moving on to larger clinical trials (see NOT-MH-11-015 <http://grants.nih.gov/grants/guide/notice-files/NOT-MH-11-015.html>).
- Develop, test and validate reliable and stable biomarkers that can identify at-risk individuals prior to disease onset, improve diagnosis, predict treatment response, or to measure disease progression. Biomarkers are also needed in clinical trials to identify dose ranges, to identify a specific subpopulation of subjects to enroll in a treatment trial, or to measure efficacy or toxicity/side effects.
- Develop clinical risk assessment instruments that encompass multiple domains (e.g., genetic, neurobiological, and environmental), are sensitive to developmental stage, and have high predictive power for the onset or recurrence of mental illness.
- Develop novel and targeted interventions (pharmacological, behavioral, or devices) that affect particular neural circuits and signaling pathways relevant to the developmental trajectory of the disease.

Prospective applicants are strongly encouraged to contact Dr. Margaret Grabb (listed below) with questions about the relevance of their interests to the mission of this division.

Division of AIDS Research (DAR)

The NIMH DAR supports scientific research to understand and alleviate the consequences of HIV infection on the central nervous system, and research to strengthen the provision and outcomes of HIV/AIDS prevention and treatment. High-priority research areas for SBIR/STTR applications are described below.

- Develop and test novel, non-invasive diagnostic approaches (instrumentation, imaging, biomarkers, central nervous system [CNS] cell-based *in vitro* models) to detect neurocognitive dysfunction associated with HIV-1 infection and innovative technologies to study the mechanisms involved in HIV-1 associated neuropathogenesis and persistence of HIV-1 in the CNS.

- Design and test novel therapeutic strategies aimed at amelioration of HIV-1 associated neurocognitive disorders (HAND) and eradication of HIV-1 from CNS reservoirs.
- Discover and develop innovative technologies for targeting therapies to the brain, including antiretroviral drugs and neuroprotective strategies with improved capability to cross the blood-brain barrier for amelioration of HAND.
- Design new strategies to reduce adverse effects of anti-retroviral drugs such as neuropsychiatric side effects and drug-drug interactions.
- Develop innovative approaches to detect and treat HIV-associated opportunistic and co-infections and co-morbidities associated with aging.
- Develop or adapt neurological/neuropsychological/neurobehavioral assessments to evaluate HIV-1 associated abnormalities in adults or children in resource poor environments that are adaptable to different cultures and languages.
- Develop innovative approaches to improve the scientific assessment of HIV sexual risk behavior through remote sensing devices, biomarkers, or other novel methods.
- Develop novel tools and approaches to identify, recruit, enroll, and/or retain those most vulnerable to HIV/AIDS (e.g., African-American MSM, adolescents) in HIV prevention research and/or initiatives.
- Develop and test tools, curricula, or other approaches designed to facilitate the effective implementation of emerging biomedical HIV prevention methods (e.g., pre-exposure prophylaxis, microbicides, circumcision, etc.), including but not limited to approaches that address behavioral aspects of biomedical prevention (e.g., provider knowledge and training; patient uptake, adherence, HIV screening, and risk-reduction counseling; adverse event monitoring, etc.).
- Develop or adapt and evidence-based HIV sexual risk reduction, psychosocial coping, or treatment adherence interventions for delivery through the internet or mobile devices, with the aim of expanding intervention access, fidelity of delivery, and/or intervention tailoring.
- Develop novel tools and approaches designed to improve HIV treatment outcomes by rapidly linking individuals diagnosed with HIV to primary medical care, enhancing patient readiness for initiation of antiretroviral medications, improving and sustaining patient adherence to antiretroviral medications, and/or improving patient retention in medical care.
- Develop innovative approaches designed to improve the quality of HIV testing, counseling, prevention, and treatment services by strengthening patient-provider communication and/or modifying the decision-making processes and practice behaviors of health care providers.
- Develop novel information technology tools designed to improve dissemination of evidence-based interventions and assist healthcare providers, community-based organizations, and professional or advocacy organizations in identifying, adopting, and implementing proven HIV prevention and treatment interventions.

Prospective applicants are strongly encouraged to contact Dr. Michael Stirratt (listed below) with questions about the relevance of their interests to the mission of this division.

Division of Services and Intervention Research (DSIR)

The Division of Services and Intervention Research (DSIR) supports two critical areas of research:

- Intervention research to evaluate the effectiveness of pharmacologic, psychosocial, somatic, rehabilitative and combination interventions on mental and behavior disorders-including acute and longer-term therapeutic effects on functioning across domains for children, adolescents, and adults.
- Mental health services research to improve the access, cost, quality and outcomes of mental health care, as well as improve the dissemination and implementation of effective interventions in clinical and community settings.

The intervention research focus is broad and inclusive with respect to the heterogeneity of patients, the severity and chronicity of disorders, and the variety of community and institutional treatment settings.

Examples of areas of interest are:

- Randomized clinical trials evaluating the effectiveness of known efficacious interventions.
- Analyses of naturalistic databases to evaluate the effectiveness of known efficacious interventions.
- Identifying moderators and mediators of intervention effects as a step to design and test personalized interventions.
- Evaluating the combined or sequential use of interventions.
- Determining the optimal length of intervention, establishing the utility of continuation or maintenance treatment (that is, for prevention of relapse or recurrence).
- Evaluating the long-term impact of efficacious interventions on symptoms, functioning, and quality of life.

Services research covers all mental health services research issues across the lifespan and disorders, including but not limited to:

- Services organization, delivery (process and receipt of care), and related health economics at the individual, clinical, program, community and systems levels in specialty mental health, general health, and other delivery settings (such as the workplace).
- Interventions to improve the quality and outcomes of care.
- Enhanced capacity for conducting services research.
- The clinical epidemiology of mental disorders across all clinical and service settings.
- The dissemination and implementation of evidence-based interventions into service settings.

In this Division, the SBIR and STTR Programs support research and development of novel tools related to clinical trials (including preventive, treatment, and rehabilitative interventions alone and/or in combination), methodology, clinical epidemiology, services research, effectiveness research, health disparities (including rural populations) and the dissemination and implementation of evidence-based treatments/research into clinical and community settings in areas directly related to the mission of the NIMH. Such tools may include applied behavioral science and technology, software, hardware and associated technologies. Also supported is research and the development or adaptation of tools and technologies to be used to enhance the training and development of new generations of researchers and practitioners and to keep established researchers and practitioners up-to-date on the findings, implementation, and methods of interventions and services research.

Prospective applicants are strongly encouraged to contact Dr. Adam Haim (listed below) with questions about the relevance of their interests to the mission of this division.

Program Contacts

Margaret Grabb, Ph.D. (general questions about the NIMH SBIR program, Phase IIB program, DNBBS, DATR, DDTR divisional interests)

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6001 Executive Boulevard, Room 7201, MSC 9645
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Adam Haim, Ph.D. (DSIR divisional interests)
Division of Services and Intervention Research
6001 Executive Boulevard
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301-445-3593
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Michael J. Stirratt, Ph.D. (DAR divisional interests)
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Gregory K. Farber, Ph.D. (general questions about technology development)
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NATIONAL INSTITUTE ON MINORITY HEALTH AND HEALTH DISPARITIES (NIMHD)

The mission of NIMHD is to lead scientific research to improve minority health and eliminate health disparities. To accomplish this, NIMHD plans, reviews, coordinates, and evaluates all minority health and health disparities research and activities of the National Institutes of Health; conducts and supports research in minority health and health disparities; promotes and supports the training of a diverse research workforce; translates and disseminates research information; and fosters innovative collaborations and partnerships.

The Small Business Innovation Research (SBIR) Program and the Small Business Technology Transfer (STTR) Program enable the Nation's small businesses to apply their unique research and development capabilities toward accomplishing NIMHD's mission.

Through small business Phase I, Phase II, and Fast-track awards, NIMHD supports multi- and trans-disciplinary research and development leading to novel and or improved products capable of contributing to NIMHD's mission. Research and development may proceed and or be initiated at the molecular, cellular, individual, community or population level. Funding support for focus groups, phase I/II clinical trials, and other studies as needed to develop and test the proposed product may be requested. Additionally, NIMHD seeks innovative strategies that engage, collaborate, or partner with health disparity communities for designing and delivering innovative products and services to improve minority health and eliminate health disparities.

An overarching objective of NIMHD's investments in SBIR/STTR programs is to ensure that health disparity populations benefit equally from innovations in health promotion and prevention, biotechnology, imaging technologies, technologies for computational biology and informatics, including for example, systems, and structural biology; and technologies designed to advance personalized medicine, electronic health records and systems, etc. New or improved instruments, devices, and related methodologies to facilitate biomedical or behavioral research and efforts that seek to redesign or design new instruments, devices, and methods likely to increase access, reduce costs, and improve quality are of special interest.

Disparities in Health Outcomes

Disparities in health outcomes are believed to result from complex interactions between many factors such as environmental exposures and genetic traits, and/or the accrual over time of stable phenotypic traits and lifestyle behaviors that contribute to but are insufficient individually to cause the onset of disease or illness. Innovations leading to improved health outcomes are of interest. Examples include, but are not limited to:

1. Multidisciplinary basic research approaches that lead to biological probes and starting points for therapeutic interventions;
2. Innovative high-throughput screening approaches to identify compounds that are active in target- and phenotype assays and to use these approaches to develop bioactive probes for application in clinical settings;
3. Methodological and technological innovations that will integrate behavioral and social science with biomedical research, including gene related and environmental components;
4. Differential pharmacologic drug metabolism;
5. Impact of dietary decision making in diverse populations and effect on health disparity outcomes; and
6. Innovations in mobile health (mHealth) and telehealth/telemedicine technologies for communication, diagnosis, monitoring, evaluation, medical management, tracking, training, and treatment in underserved community settings and rural and remote locations.

Health Promotion and Prevention Research in the Health Disparities Communities

High priority is given to activities designed to empower health disparity communities to achieve health equity through health education, disease prevention, and partnering in community-based hypothesis, outcomes- and problem-driven research. Examples of such activities include, but are not limited to:

1. Efficacy of therapies in local populations;
2. Motivating positive behavioral changes in diverse populations;

3. Health outcomes related to health seeking, lifestyle, risk taking, protective behaviors and/or socioeconomic status;
4. Incorporating research into health promotion and disease prevention initiatives, applying new knowledge in a culturally appropriate manner in intervention/disease prevention initiatives;
5. Distribution of health structures and adverse health effects, and the sufficiency of healthcare frameworks in accommodating diverse social, cultural, political and economic factors; and
6. Development and/or refinement of culturally appropriate survey instruments, tools and databases to promote community based research engaging minorities, rural and other medically underserved populations; and culturally appropriate, evidence-based health promotion and disease prevention/intervention educational media such as software, videos, printed materials for health disparities populations and disadvantaged communities.

Innovations in Health Disparities Research

Studies that promote and advance evidence-based transformations in medical decision-making and health policy; demonstration projects that implement evidence-based, culturally sensitive intervention/disease prevention therapies and diagnostics; and activities designed to build capacity for health disparities research are of high priority. Examples of such studies include, but are not limited to:

1. Development of health disparity group-specific methodologies and diagnostics;
2. Development of technologies targeted for health disparity groups (i.e., gene chips, other novel assay systems, diagnostics, animal models, specialized instruments, etc.);
3. Demonstration projects that build capacity for health disparities research (e.g., regional hospital-based registries for disease areas of emphasis, etc.) or implement the translation/application of research results in a culturally sensitive manner; and
4. Innovative technologies that enable use of electronic health record (EHR) systems and personal health records (PHR) for health disparities research. Elements could include interoperability and mapping among disparate technologies and data sets for multi-site interdisciplinary studies, innovations to enhance and accelerate participant recruitment for clinical studies, and security systems to protect storage and transmission of confidential medical data.

Development of Innovative Software and Tools for Science and Health Education

Funding support is available for the development of educational software and the application of educational technology and tools to facilitate learning of science or health science topics that target K-12 students, families, students from community, tribal, undergraduate colleges and the general public, including health service providers. Topics can range from basic biological, behavioral, social and physical sciences to specific human diseases, disorders, and conditions. Examples include but are not limited to obesity, nutrition, regenerative medicine, bioengineering, and how different parts of the body work across the lifespan, healthy living and lifestyle, mental health, health services research, health promotion, and disease prevention. Development of software, technology, or tools may be directed towards new products or adaptation of existing products designed to be more efficient, more accessible, cost-effective, more culturally appropriate, and user-friendly in promoting interactive learning, dissemination and promotion of health science to diverse populations. This effort is intended to yield efficient and user-friendly, culturally appropriate and effective educational units that can be extended to enhance the health science literacy of the general public or segments of the general public.

Examples of suitable topics include:

1. Web-based, stand-alone computational tools, instructional software or other interactive media for dissemination of science education;

2. Curriculum materials, Interactive teaching aids, models for classroom instruction, and teacher education workshops;
3. Development of health promotion and disease prevention/intervention materials such as informational videos and/or print materials and programs which are culturally appropriate for diverse populations and special communities;
4. Development and/or refinement of culturally appropriate survey instruments, tools and databases to promote community-based research engaging minorities, and rural and other medically underserved populations;
5. Development of methodologies, diagnostics, technologies, equipment, assay systems and portable devices that can be used in community settings, such as health centers, neighborhood clinics, doctors offices, public schools, libraries, and rural and remote locations to facilitate biomedical and behavioral research;
6. Development of culturally appropriate educational materials for health promotion and disease prevention/intervention such as: software, videos, printed material to facilitate translation and dissemination of evidence-based health information; and
7. Innovative applications of health information technology, including telemedicine/telehealth tools and technologies, to facilitate electronic health information exchange, enable clinical research at the point of care, and improve access to quality health care for hard to reach populations.

For additional information about the areas of interest to the NIMHD, please visit our home page at <http://www.nimhd.nih.gov/>.

For additional information on research topics, contact:

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6707 Democracy Blvd.
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For administrative and business management questions, contact:

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NATIONAL INSTITUTE OF NEUROLOGICAL DISORDERS AND STROKE (NINDS)

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.

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. 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

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
Email: mcgavernlm@ninds.nih.gov

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. Applicants are strongly encouraged to consult with Dr. David Jett to determine the programmatic relevance of their proposed research.

David A. Jett, Ph.D.

Program Director, NIH CounterACT Research
301-496-6035
Email: jetttd@ninds.nih.gov

For additional information on research topics, contact:

Ms. Stephanie Fertig, M.B.A.
Research Project Manager, Small Business Programs
301-496-1447, Fax: 301-480-1080
Email: fertigs@ninds.nih.gov

For administrative and business management questions, contact:

Ms. Tijuanna Decoster
Chief, Grants Management Branch
301-496-9231, Fax: 301-402-4370
Email: decostert@mail.nih.gov

NATIONAL INSTITUTE OF NURSING RESEARCH (NINR)

The National Institute of Nursing Research (NINR) supports research focused on biological and behavioral aspects of critical health problems that confront the Nation. Emphasis is on seeking ways to reduce the burden of illness and disability by understanding and easing the effects of acute and chronic illness, improving health-related quality of life by preventing or delaying the onset of disease or slowing its progression, establishing better approaches to promote health and prevent disease, and improving clinical environments by testing interventions that influence patient health outcomes and reduce costs and demand for care.

For additional information about areas of interest to the NINR, please visit our home page at <http://www.nih.gov/ninr/>.

Research and Development of Technologies for Health Promotion and Alleviation, Adaptation to, or Management of Symptoms

- A. Technologies to be used in the hospital, long-term care, hospice, assisted living facility, or home setting that improve symptom evaluation in persons with chronic conditions. Conditions of interest include congestive heart failure, cystic fibrosis, organ failure, cognitive impairment, renal disease, asthma, diabetes, or mobility impairments.
- B. Devices that improve the acceptance and use of assistive and monitoring devices, e.g., child peak flow measurement in the home and at school; nightly use of continuous positive airway pressure (CPAP).
- C. Devices to diagnose and screen for COPD early in the course of the disease, particularly targeting young adults.
- D. Technologies to assist in adolescent health promotion and prevention activities such as smoking cessation devices or obesity prevention technologies.
- E. Devices to assist in providing palliative care for patients with life threatening illnesses through the disease trajectory whether in active treatment or at the end of life.
- F. Technologies to assist individuals in reducing environmental exposures, i.e., chemical and viral agents, and indoor/outdoor allergens.

- G. Devices to facilitate resource sharing such as: technologies that will enable valid and reliable measurement tools/instruments to be readily available and shared by research scientist focused on similar issues in a variety of populations.
- H. Adaptation of existing or development of new technologies that will link under-represented populations with available resources to sustain healthy life styles and eliminate health disparities.

Research and Development of Technologies to Enhance Self Care and Clinical Care

- A. Technologies to assist patients to adhere to chronic regimens such as reminding children to take steroid inhalers during the day for asthma; alerting obese adults when high calorie and fat content foods are about to be eaten; adhering to medication regimens; and prompting sedentary adults to exercise.
- B. Devices that improve delivery of care to persons who have restricted or impaired movement due to (1) conditions of neurological disease or injury, peripheral vascular disease, rheumatoid disease, or intractable pain, (2) life sustaining equipment, such as dialysis machines or left ventricular assist devices, or (3) orthopedic fixation devices.
- C. Devices to enable providers and or research scientists to monitor successful adherence to complex medication regimens (e.g., Highly Active Anti-Retroviral treatment).
- D. Technologies that monitor short and long term self-care behavior changes.
- E. Biological and behavioral monitoring devices for patients in at-risk and underserved populations in rural and frontier areas that will enable access to clinical care.
- F. Telehealth technologies to improve patient outcomes through increasing quality, type, and speed of health information sharing, e.g., assessing traumatic injury severity at remote sites and transmitting this information to acute care settings for assessment and evaluation; communicating signs and symptoms of clients at home to health care providers in distant locations; tailoring care for diverse patients in a wide variety of settings, and promoting community interventions to eliminate health disparities.
- G. Technologies to treat chronic wounds that fail to heal, specifically decubitus ulcers, venous stasis ulcers, and diabetic ulcers.
- H. Technologies to be used in the hospital or home care setting to monitor or assess preterm, low-birth weight or other high-risk infants.
- I. Technologies to assist informal caregivers in providing care or assistance to family members in the home.
- J. Noninvasive devices to assess exposure to chemical and viral agents for children and adults and transmit this information to health care personnel for assessment and evaluation.
- K. Technologies to disseminate research information (i.e., biobehavioral responses, communication of risk, bioethics) to nurses practicing in emergency settings and in the community.

Other Research Topic(s) Within the Mission of the Institute

- A. ***Micro- and Nano-Systems, Platform Technologies.*** Development of BioMEMS, microfluidics and nanoscale technologies, including micro-total analysis systems, arrays, and biochips, for detection and quantitation of clinically relevant analytes in complex matrices. Application areas include biomedical research, clinical laboratory diagnostics, biodefense, high-throughput screening, drug delivery, tissue engineering, and implantable devices, among others.
- B. ***Nanotechnology.*** Research and development of new enabling technologies for the fabrication and use of nanoscale components and systems in diagnostic and therapeutic applications. Examples include: development of new nanoscale patterning and manipulation systems; new approaches to

the sensing and quantification of biologically important molecules using nanoscale specific properties; studies relating to the safety and commercialization of nanotechnology-enabled biomedical products.

For additional information on research topics, contact:

Dr. Paul Cotton
Program Director
National Institute of Nursing Research
301-402-6423, Fax: 301-480-8260
Email: Paul.Cotton@nih.gov

For administrative and business management questions, contact:

Mr. Brian Albertini
Chief, Grants and Contracts Management
National Institute of Nursing Research
Office of Grants and Contracts Management
6701 Democracy Boulevard, Room 710
One Democracy Plaza, MSC 4870
Bethesda, MD 20892-4870
(Courier delivery: Bethesda, MD 20817)
301-594-6869, Fax: 301-402-4502
Email: albertib2@mail.nih.gov

NATIONAL CENTER FOR ADVANCING TRANSLATIONAL SCIENCES (NCATS)

NCATS provides laboratory scientists and clinical researchers with the environments and tools they need to understand, detect, treat, and prevent a wide range of diseases. This support enables discoveries that begin at a molecular and cellular level to move to animal-based studies, and then are translated to patient-oriented clinical research, resulting in cures and treatments for both common and rare diseases. Through the small business Phase I, Phase II, Fast-track and Competing Renewal awards, NCATS supports primary research to create and develop critical resources, models, and technologies; including high-throughput informatics technologies that provide comprehensive answers to complex questions.

A description of NCATS program topics follows the description of our Phase IIB Competing Renewal Awards. For additional information, please visit our home page at <http://www.ncats.nih.gov>.

Phase IIB Competing Renewal Awards

NCATS will accept Phase IIB SBIR Competing Renewal grant applications to continue research and development of complex instrumentation and tools for basic, translational or clinical research where extraordinary time and effort is needed for their research and development. The Phase IIB Competing Renewal award is intended to allow small businesses the opportunity to reach to a stage where interest and investment by third parties would be more likely. Such products are expected to have a broad applicability, consistent with the mission of NCATS. Budgets that do not exceed \$1 M per year in total costs (for up to 3 years), may be requested for this Phase IIB Competing Renewal opportunity, although it is expected that in most cases the requested budget would not exceed the final year budget of the applicant's previous phase II award. This opportunity is available for the SBIR program only.

Please contact your Program Officer before beginning the process of preparing a Phase IIB Competing Renewal application. In addition, prospective applicants are strongly encouraged to submit to the Program Contact (listed above), a letter of intent that includes the following information:

- Descriptive title of the proposed research
- Name, address, and telephone number of the Principal Investigator
- Names of other key personnel
- Participating organizations
- Funding Opportunity Announcement Number (e.g., PA-12-XXX)

A letter of intent is not required, is not binding, and does not enter into the review of a subsequent application. It is expected that only a few of NCATS SBIR Phase II awards will be eligible for a Phase IIB Competing Renewal grant.

1. Pre-Clinical Innovation Technology Applications

- A. Novel approaches for facilitating the discovery of therapeutics for rare and neglected tropical diseases:
1. Novel informatics approaches for repurposing known drugs for use as a therapeutic for a rare or neglected tropical disease;
 2. Innovative phenotypic assay technologies useful for performing repurposing screens of known drug collections to identify potential therapeutics for rare and neglected tropical diseases.
- B. Pre-Clinical Innovation Technology Applications - Innovations to accelerate preclinical drug development process:
1. Technologies that improve biomarker development and validation;
 2. Platform technology for drug screening that increases accuracy and decreases time and cost;
 3. Regulatory sciences innovation;
 4. Innovative technologies and methodologies that increase predictability of *in vitro* and *in vivo* animal toxicological findings for humans;
 5. Technologies that improve drug process chemistry and formulation methods;
 6. Development of *in vitro* technologies of ADME and PK studies that have high correlation to human *in vivo* data;
 7. Innovative protein production process that increase product quality and reduce time and cost;
 8. Using siRNAs as therapeutics;
 9. Developing microRNAs as therapeutic targets;
 10. Developing new transfection reagents/strategies for the delivery of nucleic acids into difficult cell systems (e.g., lymphocytes);
 11. Developing strategies/devices that improve through-put in high-content screening;
 12. Developing of diagnostic assays for rare diseases.
- C. Disease Models
1. Innovations to accelerate the development of disease in a dish models for target identification and drug efficacy testing
 - i. Stem cells derived models;
 - ii. 3D multicellular models;
 - iii. Bioengineering of tissue in a chip models: microfluidic devices.

2. Innovations to accelerate the engineering and large scale production of disease relevant cellular systems for *in vitro* testing and cell therapies
 - i. Stem cells derived models;
 - ii. 3D multicellular models;
 - iii. Bioengineering of tissue in a chip models: microfluidic devices.

D. Misc. Biology

1. Development of innovative methods for target identification in phenotypic assays (e.g. novel pull-down reagents to complement existing strategies);
2. Development of innovative methods for large scale mapping of cellular pathways modulation *in vitro* and *in vivo*;
3. Small molecule modulators of a rising new class of targets: ubiquitin specific proteases.

E. Screening & Instrumentation

1. Innovative methods/instrumentation to characterize complex multicellular systems *ex vivo/in vitro*, and monitor changes with time and treatments;
2. Innovative methods to couple mass spectrometry detection methods to screen for drug efficacy;
3. Innovative methods to couple gene sequencing methods to screen for drug efficacy;
4. Innovative methods for high throughput biophysical characterization of binding of small molecules;
5. Innovative methods for high-throughput determination of various types of cytotoxicity and precise mechanisms of toxicity;
6. Innovative methods for probing selectivity in a cellular context vs. the more traditional recombinant assay techniques (e.g. KiNativ's methods for kinase profiling. Look for comparable methods in other important areas of research DUBs, Epigenetic targets and DNA Repair Targets etc.) ;
7. Innovative methods for inexpensive high-throughput co-crystallization of small molecules with proteins.

F. Chemical Libraries

1. Development of innovative methods to obtain libraries of purified natural products to screen to expand diversity of screening collections;
2. Development of innovative methods for small molecule library design and synthesis (e.g. using cheminformatics methods for determining optimal scaffolds of interest);
3. Development of innovative methods that expand medicinal chemistry space using novel heterocycles.

2. Clinical Innovation Technology Applications

A. Innovations to accelerate the utilization of personalized medicine:

1. Biomedical materials and medical devices;
2. Medical drug, biologics, device and product development;
3. Therapeutics;
4. Drug/product delivery systems;

5. Drug-device combination products;
 6. Integrated bio-engineering and pharmacogenomic/genetic research.
- B. Innovative Health Informatics for Clinical and Translational Researchers including:
1. Data Repositories for Research: Innovations in the creation and maintenance of large scale data repositories, designed specifically to support translational research use cases; including patient-centered outcomes research.
 2. Participant Recruitment Tools and Strategies: Innovations in Informatics to enhance and accelerate participant recruitment for clinical studies.
 3. Clinical Information Systems and Research Study Management Systems: New means to identify, link and export research-relevant data from electronic health records.
 4. Research Portal Innovations: innovations in the creation and maintenance of research portals that facilitate investigator-initiated identification of research resources and potential collaborators; support document management navigation and access to institutional core resources; monitor regulatory process improvement, track investigator use of services; and provide dashboards to monitor project-specific financial information and progress of regulatory reviews.
 5. Software development for pharmaceutical project management that increases effectiveness of managing multi-stakeholder projects, auditable databases, integration of reports and cost effectiveness.
- C. Innovative technologies that enable use of electronic medical records (EHR) and personal health records (PHR) for clinical and translational research purposes. Elements could include:
1. Interoperability and mapping among technologies;
 2. Development of software to process data from multiple clinical and translational research sites;
 3. Security systems development to protect storage and transmission of confidential medical data;
 4. Development of standardizing agreements for patient privacy and protection.
- D. Innovative biomedical technologies to enhance the feasibility or improve the quality of clinical research, conducted in the neonatal intensive care unit.
- E. Innovations in the development of vectors for gene therapy, with improved:
1. Targeting of specific cells and/or tissues;
 2. Transduction and expression;
 3. Delivery to patients;
 4. Production and purification.
- F. Innovative vehicles for drug/biologics delivery for clinical use in human subjects.
- G. Innovations in tools used by patients or for patients in Mobile Health (mHealth) and TeleHealth technologies for communication, diagnosis, monitoring, evaluation, medical management, tracking, training, and treatment.
- H. Innovations in specialized medical devices and robotics for clinical use as implantable sensors, surgical instruments, and imaging devices for medical diagnostics and treatment improvements.

NATIONAL CENTER FOR COMPLEMENTARY AND ALTERNATIVE MEDICINE (NCCAM)

The mission of the National Center for Complementary and Alternative Medicine (NCCAM) is to define, through rigorous scientific investigation, the usefulness and safety of complementary and alternative

medicine interventions and their roles in improving health and health care. For a detailed description of NCCAM mission, please see <http://nccam.nih.gov/about/plans/2011/>.

The following narrative indicates the scope of projects suitable for the SBIR/STTR program that fit within the mission of NCCAM. For additional information about areas of interest to NCCAM and a listing of NCCAM's currently funded applications, please visit <http://www.nccam.nih.gov/research>. Business concerns interested in exploring SBIR/STTR grant opportunities with NCCAM are encouraged to contact NCCAM Program Officers prior to submitting an application.

Topics of Interest to NCCAM

NCCAM encourages innovative technological research and development of commercializable CAM products that would fulfill the mission of NCCAM. The application may include basic, pre-clinical, and early phase clinical studies. The areas of interest to NCCAM include but are not limited to development and validation of:

- technology for standardization and characterization of biologically active ingredients in natural products;
- technologies for taxonomic identification of botanical raw materials or detection of adulterants;
- methods for standardization and characterization of active components of mind-body medicine interventions;
- tools for the analysis of polysaccharides and polyphenols;
- botanical or botanically derived products with useful therapeutic potential including symptom management;
- technologies for the identification and characterization of bioactive metabolites derived from oral consumption of natural products;
- methods for the sustainable production of low yield natural products of commercial interest;
- biomarkers which correlate with efficacy of CAM therapies;
- standardized, reliable and economical tools that correlate with brain imaging in response to CAM treatment;
- technical imaging tools or instruments for studying manual therapies;
- CAM-based tools for pain management;
- tools, technology and instruments, including gaming technology, for the accurate assessment of adherence and/or fidelity to the use of CAM practices, interventions, and products;
- tools to improve patient-reported outcome measures of CAM clinical investigations;
- tools to improve biological and physiological outcome measures of CAM clinical investigations;
- tools to promote adoption of healthy behaviors through the use of CAM interventions;
- tools to assess the effects of CAM on healthy behaviors.

Topics That Are of Less Interest to NCCAM

The NCCAM Office of Communications is responsible for disseminating CAM information to the public. Therefore applications addressing software development or educational materials and courses (including Continuing Medical Education courses or CD's) will not be considered relevant to the NCCAM SBIR/STTR program. Also not eligible for support are applications seeking to develop cookbooks for special diets or instructional materials for clinical practice. NCCAM does not fund clinical practice other than as a component of funded clinical research.

Although applications to support the development of databases are not widely encouraged, these proposals will be considered if they are limited to aiding the taxonomic and phytochemical characterization of medicinal plants/fungi. Applicants are encouraged to contact the appropriate NCCAM Program Officer before submitting any SBIR proposals related to database development.

Other Research Topic(s) Within the Mission of the Center

For additional information on research topics, please contact:

Dr. Craig Hopp
Program Officer
6707 Democracy Blvd.
Suite 401, MSC 5475
Bethesda, MD 20892-5475
301-496-5825, Fax: 301-480-1587
Email: hoppdc@mail.nih.gov

For administrative, business management, and grant policy questions, please contact:

Mr. George Tucker, M.B.A.
Grants Management Officer
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NATIONAL LIBRARY OF MEDICINE (NLM)

The National Library of Medicine (NLM) offers support for research and development projects in biomedical informatics. NLM defines biomedical informatics as the science of optimal organization, management, presentation and utilization of information relevant to medicine and biology. The informatics projects of interest to NLM involve the application of computer and information sciences to information problems in a biomedical domain. For additional information about areas of interest to NLM and a listing of NLM funded applications, please visit <http://www.nlm.nih.gov/ep>. Business concerns interested in exploring SBIR/STTR grant opportunities with NLM are encouraged to contact the NLM representatives prior to submitting an application.

NLM's SBIR/STTR grant programs are focused on areas of particular interest from small business. The following narrative indicates the scope of projects suitable for the SBIR/STTR program that fit within the mission of NLM. They are not listed in priority order.

- Tools for managing interactive publications and /or large datasets.
- Modeling tools for climate and environmental effects on human health.

- New technologies for disaster information management.
- Tools to enable communities to use health indicators, such as the HHS Health Indicators Warehouse, to improve a community's health.
- Tools for helping consumers visualize, understand and/or use their own health information.

Other Research Topic(s) Within the Mission of the Center

For additional information on research topics, contact:

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For administrative and business management questions, contact:

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DIVISION OF PROGRAM COORDINATION, PLANNING AND STRATEGIC INITIATIVES (DPCPSI), OFFICE OF RESEARCH INFRASTRUCTURE PROGRAMS (ORIP)

ORIP provides laboratory scientists and clinical researchers with the environments and tools they need to understand, detect, treat, and prevent a wide range of diseases. This support enables discoveries that begin at a molecular and cellular level to move to animal-based studies, and then are translated to patient-oriented clinical research, resulting in cures and treatments for both common and rare diseases. Through the small business Phase I, Phase II, Fast-track and Competing Renewal awards, ORIP supports primary research to create and develop critical resources, models, and technologies; including high-throughput informatics technologies that provide comprehensive answers to complex questions. ORIP encourages the development of inquiry-based, problem solving educational games and other social media approaches to educate K-12 students, teacher and parents on health-related topics, the clinical trials process and NIH-funded basic and clinical research.

A description of ORIP program topics follows the description of our Phase IIB Competing Renewal Awards. For additional information, please visit our home page at <http://dpcpsi.nih.gov/ORIP/index.aspx>.

Phase IIB Competing Renewal Awards

ORIP will accept Phase IIB SBIR Competing Renewal grant applications to continue research and development of tools and devices for basic or translational research where extraordinary time and effort is needed for their research and development. The Phase IIB Competing Renewal award is intended to allow small businesses the opportunity to reach to a stage where interest and investment by third parties would be more likely. Such products are expected to have a broad applicability, consistent with the mission of ORIP. Budgets that do not exceed \$1 M per year in total costs (for up to 3 years), may be requested for this Phase IIB Competing Renewal opportunity, although it is expected that in most cases

the requested budget would not exceed the final year budget of the applicant's previous phase II award. This opportunity is available for the SBIR program only.

Please contact your Program Officer before beginning the process of preparing a Phase IIB Competing Renewal application. In addition, prospective applicants are strongly encouraged to submit to the Program Contact (listed above), a letter of intent that includes the following information:

- Descriptive title of the proposed research
- Name, address, and telephone number of the Principal Investigator
- Names of other key personnel
- Participating organizations
- Funding Opportunity Announcement Number (e.g., PA-12-XXX)

A letter of intent is not required, is not binding, and does not enter into the review of a subsequent application. It is expected that only a few of ORIP SBIR Phase II awards will be eligible for a Phase IIB Competing Renewal grant.

RESEARCH TOPICS OF INTEREST TO ORIP:

Research and Development in Comparative Medicine

- A. Development of improved reagents and cost-effective methods to accurately screen and diagnose selected laboratory animal diseases, and for performing overall assessments of animal quality and health status. An urgent need currently exists for the development of improved methods for the detection of active tuberculosis in nonhuman primates.
- B. Development of improved reagents and techniques for isolating and propagating embryonic and somatic stem cells from laboratory animals. Improving the methods for the efficient generation of the induced pluripotent stem cells and reprogramming of the differentiated cells to other lineages *in vitro* and *in vivo*.
- C. Development of improved reagents, techniques, and equipment for genomic and transcriptomic analysis and data mining from tissue or cells of laboratory animals and animal models of human diseases.
- D. Development of new technologies to rapidly phenotype large number of animals.
- E. Development of technologies for the identification of biomarkers for clinical diagnostic in well validated disease model.
- F. Development of vaccines and new therapeutic agents for the prevention and/or control of selected laboratory animal diseases. One high priority need is for the development of methods to control and prevent Herpes virus B in nonhuman primates.
- G. Development of commercially valuable reagents for lower organisms or established cell cultures.
- H. Development of cost-effective husbandry and colony management techniques, equipment, and/or new approaches to improve laboratory animal welfare and assure efficient and appropriate research use.
- I. Design of specialized equipment and caging for laboratory animals to permit optimal environmental control and operational efficiency.
- J. Identification, development, and characterization of spontaneous and engineered vertebrate animal models for studies on various types of human disease, excluding most random mutagenesis projects performed in rodents. Applications primarily focused on cancer should typically be directed to NCI. A need exists for a small animal model of Hepatitis C virus infection in humans. Methods to produce genetically engineered mice susceptible to HCV replication, without the requirement for

individual colonization with transplanted organs or cells in each experimental subject, are encouraged.

- K. Development and refinement of high throughput technologies for the effective cryopreservation and long-term maintenance of laboratory animal embryos, gametes, and their predecessors.
- L. Development of technologies for improved embryo transfer within a single animal species or of intraspecific embryo transfer to allow preservation of rare, unique, or endangered animal species that may have unique value as animal models for human disease.
- M. Development of improved reagents, techniques, and equipment for performing, analyzing and data capture and processing for studies of the “omics” (genomics, transcriptomics, phenomics, proteomics, glycomics, epigenomics, metabolomics) in normal and disease-condition animal models.
- N. Development of biological tools and reagents for reconstruction, remodeling, repair and regeneration of tissues damaged by injury or disease. Development of the technologies and procedures for testing efficacy and safety of these experiments in animal models. Approaches for detection and tracking of the implanted cells and tissues *in vivo*.
- O. Development of computational science-based technologies to create fast, effective community access to preclinical models-based raw data, processed data, and processing tools.
- P. Development of the *in vitro* animal cell culture techniques and *in silico* computational methods to reduce the number of animals used in studies and replace certain tests conducted in animal models with new complementary methods.

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Research and Development in Science Education

Development of Innovative and Inquiry-Oriented Software and Tools for Science and Health Education

Funding opportunities are available for the development of discovery-oriented educational software and the application of educational technology and tools for health science topics that target K-12 students, families, students from community, tribal, undergraduate colleges and the general public. Topics can range from basic biological science to specific human diseases. Examples include; but are not limited to regenerative medicine, bioengineering, the clinical trials process, how different parts of the body work across the lifespan, healthy living and lifestyle, mental health, and prevention of obesity, heart disease, diabetes, and other chronic diseases. Development of software, gaming technology, or other educational tools may be directed towards new products or adaptation of existing products designed to be more efficient, cost-effective, and user-friendly in promoting problem solving and interactive learning, dissemination and promotion of health science. This effort is intended to yield efficient and user-friendly, culturally appropriate and effective educational resources that can be extended to enhance the health science literacy and the health of the general public. A broad dissemination plan is strongly encouraged.

Examples of responsive applications may include but are not limited to:

- A. Web-based, stand-alone computational tools, instructional software or other interactive media for dissemination of science education;
- B. Curriculum materials, Interactive teaching aids, models for classroom instruction, and teacher education workshops; and

- C. Development of health promotion and disease prevention/intervention materials such as informational videos and/or print materials and programs which are culturally appropriate for populations and special communities.

Projects that target the following constituencies are strongly encouraged:

- D. K-12 students, teachers and parents.
- E. Students of community colleges, tribal colleges, undergraduate colleges and minority-serving institutions.
- F. Patients and families with health conditions that disproportionately affect minorities and other medically underserved populations, including members of disadvantaged urban and rural communities.

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Other Research Topic(s) Within the Mission of the Office of Science Education

The Science Education Partnership Award (SEPA) program within the Office of Science Education supports and fosters health-related research to build capacity at minority serving institutions and in underserved states, respectively. These programs support a wide variety of biomedical research, including clinical and translational research to reduce health disparities experienced by disadvantaged groups and medically underserved populations. Applications involving partnerships with minority-serving institutions and the Institutional Development Awards (IDeA)-eligible institutions are strongly encouraged. Topics of special interest include:

- A. Development and/or refinement of culturally appropriate survey instruments, tools and databases to promote community based research engaging minorities, rural and other medically underserved populations;
- B. Development of methodologies, diagnostics, technologies, equipment, assay systems and portable devices that can be used in community settings, such as health centers, neighborhood clinics, doctors offices, public schools, libraries, and rural and remote locations to facilitate biomedical and behavioral research;
- C. Development of culturally appropriate educational materials for health promotion and disease prevention/intervention such as: software, videos, printed material to facilitate translation and dissemination of evidence-based health information; and
- D. Innovative applications of health information technology, including telemedicine/telehealth tools and technologies, to facilitate electronic health information exchange, enable clinical research at the point of care, and improve access to quality health care for hard to reach populations.

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CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC)

CDC will accept SBIR grant applications on the April 5, August 5, and December 5, 2012 submission dates.

CDC's mission is to create the expertise, information, and tools that people and communities need to protect their health – through health promotion, prevention of disease, injury and disability, and preparedness for new health threats.

CDC seeks to accomplish its mission by working with partners throughout the nation and the world to:

- monitor health,
- detect and investigate health problems,
- conduct research to enhance prevention,
- develop and advocate sound public health policies,
- implement prevention strategies,
- promote healthy behaviors,
- foster safe and healthful environments,
- provide leadership and training.

Those functions are the backbone of CDC's mission. Each of CDC's component organizations undertakes these activities in conducting its specific programs. The steps needed to accomplish this mission are also based on scientific excellence, requiring well-trained public health practitioners and leaders dedicated to high standards of quality and ethical practice.

To keep pace with emerging public health challenges and to address the leading causes of death and disability, the CDC has begun an effort to quickly achieve measurable impact in a few targeted areas. The term "Winnable Battles" describes public health priorities with large-scale impact on health and with known, effective strategies to intervene. The charge under Winnable Battles is to identify optimal strategies and to rally resources and partnerships to accelerate a measurable impact on health.

CDC has identified these winnable battles based on the scope of the burden and our ability to make significant progress in improving outcomes. These priority areas include:

- [Food Safety](#) – Foodborne diseases affect millions of people and kill thousands in the U.S. each year.
- [Global Immunization](#) – CDC is implementing global immunization programs to eradicate polio, prevent measles and rubella, end the meningitis epidemic in Africa, accelerate the introduction of pneumococcal and rotavirus vaccines, and strengthen countries' own immunization systems.
- [Healthcare-associated Infections](#) – HAIs affect patient lives and add to our growing healthcare costs.
- [HIV](#) – There are more than 1 million people living with HIV in the U.S.
- [Lymphatic Filariasis in the Americas](#) - CDC and its partners are working to eliminate lymphatic filariasis (LF) from the areas of the Americas where the disease still exists.
- [Mother-to-Child Transmission of HIV and Congenital Syphilis](#) - CDC works with Ministries of Health and other partners to prevent HIV and syphilis from passing from mothers to babies, thus reducing the number of babies who suffer early death and/or chronic illness caused by these infections.

- [Motor Vehicle Injuries](#) – Motor vehicle-related injuries are the leading cause of death in the first three decades of life.
- [Nutrition, Physical Activity, and Obesity](#) – Excess weight contributes to many of the leading causes of death in the United States, including heart disease, stroke, diabetes, and some types of cancer.
- [Teen Pregnancy](#) – In 2009, the number of births to teenage mothers was 409,840 – a birth rate of 39.1 per 1,000 women aged 15 to 19.
- [Tobacco](#) – Tobacco use remains the leading preventable cause of disease and death in the United States.

By identifying priority strategies and clear targets and by working closely with our public health partners, we can make significant progress in reducing health disparities and the overall health burden from these diseases and conditions.

In addition CDC continues to focus on other high burden public health topics where it can make a significant impact in preventing illness, injury and disability and death. For additional information about CDC, please visit our home page at <http://www.cdc.gov>.

Questions of a general nature about the CDC SBIR program should be directed to:

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or

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NATIONAL CENTER ON BIRTH DEFECTS AND DEVELOPMENTAL DISABILITIES (NCBDDD)

For additional information about NCBDDD, please visit their web site at: <http://www.cdc.gov/ncbddd>.

1. Reducing Hospital Readmissions and Post Discharge Venous Thromboembolism (VTE) by the Use of Embodied Conversational Agents to Improve Discharge Planning and Transition of Care

Background: VTE is estimated to newly affect 300,000 to 800,000 people and to cause 60,000 to 100,000 deaths each year, making it one of the six leading causes of death in the US. About one-quarter of new cases occur during a hospital stay and another one-quarter within 3 months after discharge. Up to 50% of hospital associated VTEs can be prevented through use of prophylaxis. The DHHS Partnership for Patients has set as a goal a 50% reduction in VTE occurring prior to discharge and a 20% reduction in 30 day readmissions with VTE. Reducing VTE readmissions requires that at risk patients be educated

regarding their risk and prevention behaviors. New tools are needed to educate at risk patients and motivate them to adhere to recommended measures.

Effective discharge and transition care planning is limited by low health literacy and nursing staff time. Interactive computer software for discharge planning, utilizing Embodied Conversational Agents (ECA a.k.a avatar), shows promise in addressing both limitations. In one study 78% of patients rated overall satisfaction with the ECA as “very satisfied.” Patients with inadequate health literacy rated the ECA as favorably as patients with adequate health literacy. Redesigned discharge planning and transition of care employing ECA was associated with a 30% reduction in all-cause hospital readmission and emergency department visits within 30 days of discharge. The effectiveness of these techniques in reducing VTE associated hospital readmission has not been established. If successful such software and techniques could be readily adopted by almost all hospitals and lead to substantial reduction of VTE 30 day readmissions.

This funding opportunity invites small businesses to submit proposals to adapt interactive computer software utilizing ECA for discharge and transition planning for patients at risk of VTE to specifically address VTE prevention messages and to assess the effects on 30 day readmission rates associated with a VTE for patients who were on anticoagulation or mechanical prophylaxis while hospitalized.

Specific Research Areas of Interest: Businesses that are already active in this area are most likely to apply and will have requisite knowledge in relevant scientific program areas.

Impact and Commercialization Potential: VTE is a CMS priority hospital associated condition (HAC). Reducing in-hospital VTE is being addressed through other initiatives. Reducing 30 day readmissions after VTE will depend on improved discharge planning, patient education, and coordination of post discharge transition care. Innovative solutions utilizing ECA software have been shown to address two limitations in the discharge process and achieve substantial all cause 30 day readmissions. Similar success in reducing 30 day readmission related to VTE will be a significant public health advance. Given the priority of this condition nearly every hospital in the country will be a potential customer for an effective program. A successful program could generate substantial commercial rewards.

2. Smart Phone Applications to Help People with Disabilities Manage Their Own Care

Background: Over 50% of Americans have a chronic illness and 20% have disabilities. Chronic illness often leads to functional disability. Disability and chronic illness cost over \$260B every year, including preventable hospitalizations, emergency room visits and surgery for wounds, urinary tract infections, pneumonia, and sepsis. Clinicians could more efficiently manage patients in greater numbers through telemedicine that provides triage, timely intervention and preventative care that has traditionally been carried out in person. This proposal seeks to further develop and test a unique telemedicine portal linked to smartphone applications (apps) that enable clinicians to remotely monitor and triage the self-care activities of patients. Patients can be given apps customized to manage their own care of issues like clinical appointments, medications, supplies, bladder and bowel programs, skin integrity, depression, nutrition and exercise.

The system proposed here is unique, because it would allow patients and clinicians to have two-way-communication. The proposed system would allow patients to alert clinicians when new problems arise (e.g. urinary tract infection), report specifics about their medical problems (e.g. size of a pressure sore), ask questions, refill medications, make appointments, or seek medical advice. It would automatically send reports when gaps in care arise (e.g. medications have not been refilled). At the same time, clinicians could monitor the self-care activities being completed by patients, receive alerts when there are problems, triage large groups of patients, and intervene quickly before problems arise.

It should be customized for individual patient needs and inclusive of people with cognitive and physical impairments. The proposed system would be mobile device-friendly, capable of giving clinicians access to

data obtained from a patient's own home, work, or leisure environments. It also would allow clinicians to collect data that could then interface with existing electronic health records.

Specific Research Area of Interest: Application of smart phone technology to improve health outcomes by systematic, interactive monitoring of physical variables and adherence to intervention routines.

Impact and Commercialization Potential: By improving medical outcomes and delivery of care and reducing cost, resources could be redirected from expensive, often inaccessible, in-person care to care based on consumer-centered technology, informed decision-support and patient participation. Commercialization potential is broad and encompasses many patient groups with chronic conditions (like arthritis, obesity, cardiopulmonary disease, spina bifida and spinal cord injuries) who are seeking greater autonomy over health and wellness interventions. Mobile app downloads are predicted to jump from 7 billion in 2009 to almost 50 billion in 2012. Smartphone apps are expected to enable the mobile health industry to successfully reach out to 500 million of a total 1.4 billion Smartphone users by 2015. One-half of US health consumers are willing to engage in online care and consultation. More than 50% of physicians are using Smartphones or PDAs on a regular basis for everyday treatment activity.

3. Tool for Web-based and Smart Phone Surveys

Background: Birth defects are a serious health concern affecting 1 in 33 infants. Today, approximately 67% of birth defects have unknown causes. As part of the mission to prevent birth defects, NCBDDD is collaborating with 8 state-based grantees on the National Birth Defects Prevention Study (NBDPS). The NBDPS is an on-going, large, multi-site, population-based case-control study to identify potential genetic and environmental risk factors for birth defects. Under the NBDPS, over 29,000 case mothers and 10,000 control mothers have been interviewed as of September 2011 and over 100 articles on birth defects risk factors have been published. With the decreased use of telephone land lines and the increasing use of the internet and smart phones, alternative survey methods besides the computer assisted telephone interview (CATI) that is currently utilized for the NBDPS, are needed.

Specific Research Areas of Interest: Development and pilot testing of a prototype of a tool that survey participants can access securely via the web and/or mobile electronic devices. Attributes of the tool should include:

- 1) A secure method to access the survey via the web and mobile electronic devices. Data security is of the utmost importance as well as ease of operation for study participants and interview administrators.
- 2) A basic tool that can be freely shared to create fully customizable modular surveys in multiple languages (English/Spanish) utilizing an updateable page layout editor and question library for each survey, customizable conditional survey logic with branching and skipping, question and answer piping and validation for errors and omissions. Entry of questions and multiple choice options into the tool should be user friendly and should not require programming skills. CDC can provide sample modules to ensure compatibility and utility of the tool during development.
- 3) Built-in capacity to code free-text responses; view real-time survey results; generate ad-hoc reports; and export response data to common file formats for analysis.

Pilot testing should assess ease of use by survey staff and participants, and participant opinion of the tool.

Impact and Commercialization Potential: A web-based survey tool will be quicker and easier for survey participants to use and much less expensive to operate and maintain than telephone interviews. It will also be better for some topics (e.g. sensitive topics and information the respondent needs to look up). A user-friendly web-based survey tool would be valuable and beneficial for CDC and other federal agencies, state and local health departments, and other public health organizations to securely survey the general public about specific and multiple health issues.

For NCCDPHP programmatic information, contact:

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NATIONAL CENTER FOR CHRONIC DISEASE PREVENTION AND HEALTH PROMOTION (NCCDPHP)

For additional information about NCCDPHP, please visit their web site at:
<http://www.cdc.gov/chronicdisease/index.htm>.

1. Development of a Brief Video Intervention for Preventing Teen Pregnancy Among Female Adolescents Attending Family Planning Clinics

Background: Teen pregnancy continues to pose a health and social burden in many US communities, particularly among racial/ethnic minorities, and has been deemed a CDC Winnable Battle. Most evidence-based behavioral interventions related to teen pregnancy prevention, however, are multi-session, group- or individual-level, and require substantial resource investments and time commitments from providers and clients. These interventions can be difficult to implement at scale and to sustain over time. Conversely, simple interventions, such as video interventions, can effectively deliver prevention messages because of their relative low cost, ease of implementation, likely acceptability, broad reach, and high likelihood of being adopted and sustained. There is increasing evidence that video interventions can reduce adverse reproductive outcomes. For example, a 23-minute “soap opera” style waiting room-delivered video-based intervention, *Safe in the City*, recently was shown to reduce new sexually transmitted diseases by nearly 10% among a study sample of approximately 40,000 high-risk inner-city STD clinic patients (see <http://www.stdcentral.org/SitC>). The proposed activity will result in development of a new video that contains the elements contained in a video-based intervention such as *Safe in the City* that integrates prevention messages regarding unintended pregnancy into an appealing product for adolescents at high risk of unintended pregnancy. The intervention should be designed in such a way as to directly impact rates of unintended pregnancy.

Specific Research Areas of Interest: The proposed activity will require an applicant with experience developing video interventions in sexual and reproductive health or related areas, expertise in use of behavior change theory to guide intervention development, working with interdisciplinary groups such as governmental agencies and community advisory boards. CDC is further interested in the applicant conducting formative research to explore strategies for enhancing message appeal for young women

(e.g., focus groups and in-depth interviews), and understanding of implementation issues across clinical settings in which the new video could be used. Enhancements to the video structure (e.g., gaming) to further engage viewers is encouraged. One awardee will develop the video through an iterative process with appropriate subject matter experts to ensure broad appeal and acceptability of characters, content, and design. Given that most evidenced-based programs for teen pregnancy prevention have examined the impact on sexual risk behavior as a proxy for teen pregnancy rates, future activities could include an evaluation of effectiveness of the video on teen pregnancy rates directly.

Impact and Commercialization Potential: Video interventions offer immediate public health benefit because the simplicity of the intervention permits wide reach and immediate dissemination capability. In the Safe in the City example, dissemination to community partners began the day the primary outcome article was published whereas this process of dissemination typically requires two or more years to complete for other effective behavioral interventions. In the first 12 months of availability, more than 2,000 clinics (i.e., STD clinics, family planning clinics, and community health settings) requested the video, and a six month follow-up evaluation of clinic directors has shown high intervention uptake. From a marketing perspective, development of a health video for purchase offers commercialization opportunities for applicants.

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NATIONAL CENTER FOR HIV/AIDS, VIRAL HEPATITIS, STD, AND TB PREVENTION (NCHHSTP)

For additional information about NCHHSTP, please visit their web site at: <http://www.cdc.gov/nchhstp/>.

1. Development of a Desktop/Smartphone Software Application for Patients Using Antiretroviral Prophylaxis for HIV Prevention

Background: The National HIV/AIDS Strategy tasks CDC to develop, evaluate, and disseminate interventions to reduce HIV incidence in the US (one of CDC's Winnable Battles). Effective use of antiretroviral prophylaxis for HIV prevention requires that tools be provided to patients and their providers to help identify levels of risk for HIV acquisition, provide plain language guidance to patients of all literacy levels, and support adherence to medications and clinical monitoring. Mobile devices (e.g., smartphones) and desktop applications are ideally suited for these purposes because they allow individuals to tailor use

according to individual needs, and can facilitate sharing of information between patients and providers. According to one recent survey, 1 in 6 mobile subscribers own a smartphone and many who do not, have access to computers at work, home, or in public spaces (e.g., public libraries).

Specific Research Areas of Interest: The development of this technology should include some or all of the following features: 1) an HIV risk calculator (e.g., <http://www.rmdstudio.com/projects/94-coronary-heart-disease-risk-calculator-iphone-app>) that incorporates behavioral, demographic, and local prevalence factors using a GPS or zip code look-up function (e.g., <http://www.aidsvu.org>), 2) a medication adherence reminder and monitoring function (e.g., <http://www.dosecast.com>), 3) a symptom checklist with prompts for urgent physician contact when indicated (e.g., http://www.ihealthventures.com/app_details.php?aid=107970), 4) a clinical visit reminder function (e.g., http://www.ihealthventures.com/app_details.php?aid=99707), and 5) access to plain language, graphical displays of information for low-literacy users. Additional potential features include: support for push to peer support network sites (e.g., <http://www.caringbridge.org/>), methods (with unique identifiers) to allow an option of sharing information with clinical providers (e.g., <http://www.welldocinc.com/Products-and-Services/Our-Products.aspx>) that meet all applicable federal security standards for confidential or personal data, and support for risk behavior monitoring over time (e.g., <http://www.livestrong.com/quit-smoking-app/>).

Impact and Commercialization Potential: High efficacy of antiretroviral prophylaxis in preventing HIV infection is only achieved with high adherence to daily medication and safe use requires regular clinical monitoring visits. Yet early studies indicate that adherence and persistence in care are often lower than needed (in some studies <50%). Mobile personal health applications are widely available for non-HIV conditions but this product would fill a needed market for HIV prevention in clinical settings. The personal “app” market has demonstrated significant commercialization potential and the anticipated number of users for this application would be significant.

For NCHHSTP programmatic information, contact:

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NATIONAL CENTER FOR INJURY PREVENTION AND CONTROL (NCIPC)

For additional information about NCIPC, please visit their web site at:
<http://www.cdc.gov/injury/index.html>.

1. Comfortable and Inexpensive Life Jacket to Increase Wear

Background: Each year, the U.S. Coast Guard received reports over 4,500 boating incidents where more than 3,000 boaters are injured, and around 700 die. Among those who drowned, 9 out of 10 were not wearing life jackets. Most boating fatalities are caused by drowning with 90% of victims not wearing life jackets (Centers for Disease Control and Prevention. Wide-ranging OnLine Data for Epidemiologic Research (WONDER) [online]. (2010) Available from URL: <http://wonder.cdc.gov/mortsql.html>).

For those who take to the water for occupational purposes, the U.S. Coast Guard (USCG) estimates during 1982-1987, the annual occupational fatality rate for U.S. commercial fishermen was 47 deaths per 100,000 workers. The major cause of these deaths was drowning. According to information gathered by CDC's Alaska Activity, the occupational fatality rate for commercial fishermen in Alaska during 1991-1993 was 195 deaths per 100,000 workers -- nearly 30 times the average annual rate for all U.S. workers. Of these 195 deaths, 91% were caused by drowning. Data clearly show that life jackets greatly increase the chances of survival for fishermen: 63% of fishermen wearing life jackets when they jumped or fell into the water survived, whereas only 12% of those without life jackets survived. These conclusions and recommendations may apply to all commercial fishing operations in the United States.

Public Health Impact: Studies have shown that the majority of drowning incidents were precipitated by unexpected entry into the water, which means the victim had no time to grab a life jacket before entering the water. Many of the drowning incidents could have been prevented by wearing a life jacket. Common reasons given for not wearing a life jacket include being 1) uncomfortable and 2) expensive. A newly designed life jacket that addressed these issues has the potential to increase use and decrease morbidity and mortality from drowning. It is believed that a wide array of retail and commercial outlets (specialty outdoor retail stores, warehouse stores, and convenience stores) will have an interest in this product.

Specific Research Areas of Interest: To develop a comfortable, lightweight, compact, inexpensive, and easy to use life jacket that could be worn for recreational and/or occupational activities (boating, kayaking, fishing, etc.) to reduce the risk of drowning.

2. Information Technology Development for Relaying Injury Severity of Motor Vehicle Occupants to Emergency Medical Personnel

Background: Motor vehicle crashes (MVCs) have been noted as a leading cause of death and injury among adults and children in the United States. In 2009, more than two million adults were treated in emergency rooms for injuries related to motor vehicle crashes. Therefore, the Centers for Disease Control and Prevention (CDC) has identified this problem as a winnable public health battle and has focused efforts on the prevention of crashes as well as reducing the effects of crashes after they occur.

One method of decreasing the effects of motor vehicle crashes is the development of Advanced Automatic Collision Notification (AACN) systems. AACN systems are described as a mechanism of sensors placed in automobiles that will activate during events such as airbag deployment or tightening of seatbelt pre-tensioners and will subsequently initiate an emergency wireless call to a telematics service provider. This system can then deliver such information as GPS location of the vehicle along with crash-related data that can be used by emergency responders and will also open a voice channel for communication with the driver. Development of AACN technology includes prediction of injury scores for passengers in the vehicle using data such as speed of the vehicle, change in velocity, number of persons in the vehicle at the time of crash and other data pertinent to optimal field triage of victims. The use of this type of system is proposed to decrease response time to vehicle crashes and in turn will save lives.

A current area of discussion in AACN is how to transmit predicted injury scores to emergency medical personnel in real time in order to efficiently allocate emergency health services. This includes dispatching emergency medical personnel, activation of trauma centers if needed and providing medical personnel with accurate information on injury severity that will aid in the delivery of care once the injured occupant arrives at a definitive care location.

Public Health Impact: Research has indicated that reducing time to definitive care can reduce mortality by up to twenty-five percent. Much of this care for severely injured patients is provided at trauma centers. Therefore, development of mechanisms that can quickly and accurately relay injury information to all medical personnel can reduce both the morbidity and mortality of injured motor vehicle occupants as well as reduce healthcare costs by providing real time information for efficient allocation of services.

Examples of specific research areas of interest, but not limited to: The CDC is interested in the development of methods to communicate predicted injury scores in real time across the continuum of emergency medical services. This will entail the creation of new medical decision making models and the necessary technologies that inform not only AACN providers and first responders, but also definitive care providers such as trauma surgeons and emergency department personnel. Crash information that is collected at the time of crash and transmitted in real time to all levels of emergency medical response will reduce time to definitive care, and prepare providers with quick and reliable information that will result in decreased morbidity and mortality.

3. Innovations in Electronic Medical Record (EMR) Systems to Reduce Older Adult Falls

Background: Falls and their associated injuries are a growing public health concern—responsible for over 19,000 deaths and 2.2 million emergency department visits nationwide, and costing over \$28 billion annually. Clinical assessment and individualized risk factor reduction is effective in reducing falls and fall injuries. The American Geriatrics Society (AGS) has published practice guidelines to promote falls risk assessment and management. However, awareness of the AGS guidelines among health care providers is low. Primary care providers report that they do not know how to assess fall risk or do not have adequate knowledge about fall prevention. To address these concerns and fill this identified knowledge gap, CDC has used the AGS guidelines in conjunction with formative research methods to develop STEADI, a comprehensive fall prevention toolkit for healthcare providers.

Public Health Impact: The US population is ageing. People aged 85 and older are the fastest growing segment of the elderly population as well as those with the highest risk of falls and fall injuries. On an individual basis, healthcare providers can prevent falls through clinical falls risk assessment, treatment and referral. This process could be streamlined by integrating the STEADI provider toolkit into electronic medical records (EMR) systems. Such an integrated system would facilitate the assessment process and simplify referrals to appropriate providers, as well as demonstrate cost savings by reducing fall-related injuries and hospitalizations.

Specific research areas of interest: CDC is interested in the development of EMR-compatible technology that will facilitate healthcare providers' use of fall risk assessment procedures, treatment, and referral within the office practice setting and would simultaneously streamline health care reimbursement procedures. Such technology would help providers improve clinical care while at the same time increasing efficiency, improving patients' health outcomes, and lowering health care costs related to falls and fall injuries.

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NATIONAL CENTER FOR IMMUNIZATION AND RESPIRATORY DISEASES (NCIRD)

For additional information about NCIRD, please visit their web site at: <http://www.cdc.gov/NCIRD/>.

1. Development of Near-Patient Point-of-Care Diagnostic Tests for Anthrax

Background: *Bacillus anthracis* is a high consequence Category A Select Agent pathogen that causes anthrax. The general ease with which infectious *B. anthracis* spores may be aerosolized and inhaled, together with the stability and persistence of spores in the environment and the high mortality rate of systemic anthrax make *B. anthracis* a high potential bioterrorist (BT) weapon.

In a BT event of unknown etiology or agent, two categories of diagnostic tests will have high priority; 1) broad spectrum tests that detect onset of uncharacterized disease/infection in the exposed population and 2) agent specific diagnostics of high positive predictive value (PPV, 'rule in') and negative predictive value (NPV, 'rule out') for specific diseases in asymptomatic and symptomatic persons. During an anthrax emergency the recommended post-exposure prophylaxis is vaccination and a concomitant 60 day course of antibiotics. Prompt and accurate diagnosis of symptomatic individuals will ensure accurate treatment and save lives. The primary purpose of an asymptomatic infection test would be to determine non-exposed, exposed and infected individuals and to triage the cohorts to the appropriate care for the BT agent and to determine that an individual could discontinue post-exposure prophylaxis. Asymptomatic infection tests have additional non-medical applications, including triage and reducing fears among concerned citizens, which in turn, may prevent large numbers of asymptomatic individuals from descending on medical facilities.

Critical to the success of an emergency response is the ability to administer these types of tests to large numbers people and to provide timely results in a 'near patient' setting. Consequently these tests must be field deployable and have either a low resource requirement (e.g. lateral flow assays with visual readout) or harness established, widely used point-of-care technologies (e.g. as used for blood glucose monitoring).

Specific Research Areas of Interest: The most effective early diagnostic test for *B. anthracis* infection is detection of anthrax toxins in the blood. This approach is also advantageous in monitoring the effectiveness of medical countermeasure intervention. However, the current best practices for quantifying anthrax toxemia are laboratory based and require specialized equipment.

CDC has prepared a panel of key reagents that potentially may be developed into high sensitivity and specificity 'near-patient' point of care tests. CDC holds intellectual property on certain aspects of these reagents. The objective of this SBIR will be to develop these reagent panels to provide high specificity, high sensitivity field deployable tests for early identification of *B. anthracis* infection that are not negated by antimicrobial or vaccine interventions.

Impact and Commercialization Potential: *In vitro* diagnostic assays have a critical role in defining the medical needs and expediting the appropriate prophylaxis of an exposed population following a BT event. In the 2001 anthrax letter events, using the post-mark date as the exposure time point, the median number of days to onset of illness in the first case cluster was 10 days (range 4-13 days) and in the

second cluster it was 7 days (range 5-13). The incubation period of disease was estimated at 4.5 days. In these individuals, on average, those who survived inhalation anthrax started antimicrobial treatment 4.7 days after symptom onset. Those who died started antibiotic treatment 5.8 days after symptom onset. The rapid and early diagnosis of case-patients with anthrax is therefore of paramount importance in saving lives.

2. Commercialization of a Serologic Kit for Pertussis

Background: Pertussis, also known as whooping cough, is the most poorly controlled childhood vaccine preventable disease with 27,550 U.S. cases reported in 2010. The etiologic agent, *Bordetella pertussis* is a fastidious organism and difficulties associated with diagnosis by culture or polymerase chain reaction (PCR) make public health surveillance challenging. Isolation of *B. pertussis* by culture requires several days to perform and suffers from a lack of sensitivity. PCR can provide increased sensitivity and more timely results but similarly to culture, the sensitivity of PCR decreases with the duration of cough. Therefore, it is a useful tool for diagnosis only for the first three to four weeks of coughing.

Serologic testing for pertussis infection has the potential advantage of markedly improving diagnostic sensitivity. Serologic measurement of pertussis antibodies would be helpful in cases where paroxysmal coughing has been present for weeks (2 to 8 weeks) or in adults in whom the typical features of pertussis are absent. Currently, except for Massachusetts, the Council of State and Territorial Epidemiologists (CSTE) case definition does not include serologic confirmation; however, multiple serologic tests with unknown clinical accuracy are commercially available. CDC in collaboration with Center for Biologics Research and Review (CBRR), US Federal Drug Administration (FDA) has developed and analytically validated a single serum/single dilution IgG anti-pertussis toxin (PT) enzyme-linked immunosorbent assay (ELISA) for diagnosis of pertussis, using the cut-off of 94 International Units (IU)/mL. This quantitative and qualitative assay has proven very useful in confirming pertussis outbreaks and efforts for its clinical validation are underway with testing of over 700 individuals with cough illness completed. Improving laboratory testing capabilities is essential to meet public health objectives for the prevention and control of *B. pertussis* infections. The overall aim of this proposal is to ensure that a validated serodiagnosis assay is commercially available for surveillance, control and prevention of pertussis.

Specific Research Areas of Interest: CDC has prepared a panel of key reagents including 6 standards and 3 controls that potentially may be developed into a high sensitivity and specificity commercial serodiagnosis test for pertussis. Before serodiagnosis can be used in pertussis surveillance, possible interfering factors, such as recent vaccination with a vaccine containing the same component as that measured by the ELISA, need to be identified. Recent CDC kinetic data (Pawloski et al 9th International *Bordetella* Symposium, 2010) have demonstrated that receipt of Tdap vaccination six months before testing did not confound interpretation of this ELISA. This seroassay remains a valuable diagnostic tool for adult pertussis infection even after Tdap vaccination. The objective of this SBIR will be to make this assay widely available as a commercial kit to be used for identification of *B. pertussis* infection during the late stage of disease when culture or PCR are no longer positive.

Impact and Commercialization Potential: CDC and FDA co-own the intellectual property of this *in vitro* diagnostic test as published (Clin. Vaccine Immunol., 6:1781-8, 2009) and propose to make it a marketable product that can be accessed by local and state public health institutions as well as reference labs involved with pertussis diagnosis.

3. Kenya Enhanced Cookstoves for Health (KECH)

Background: Indoor smoke from cooking with biomass fuels leads to over 1.5 million premature deaths each year, world-wide. In particular, acute respiratory infections (ARI) cause nearly one-fifth of child mortality globally. Poor indoor air quality is a recognized risk factor for ARI in children (Wall, 2000; Bruce, 2000). Much of the poor indoor air quality in developing countries is attributed to incomplete combustion of biomass using simple stoves, such as the three-stone firepits used in rural Kenya. Improved stoves

have been developed that decrease smoke output and are relatively simple to construct with locally available materials and skilled labor. However, results from pilot studies evaluating locally produced suggest that, although these stoves remove visible smoke and are very acceptable to the local population (>2200 sold), they were not found to be effective in reducing particles less than 2.5 microns in diameter (PM_{2.5}) to levels of exposure that would likely have an impact on childhood pneumonia and health outcomes.

Specific Research Areas of Interest: The goal of this program is to develop technology to enhance the performance of existing biomass cookstoves to reduce particulate emissions (PM_{2.5}) by $\geq 85\%$ as compared to the traditional three-stone fire. A reduction in emission at this level is expected to have significant impact on child and maternal health.

Phase I: Conduct a feasibility demonstration of a proposed stove enhancement technology with an existing stove to show a $\geq 85\%$ reduction in emissions as compared to the traditional three-stone fire. This will involve the development and testing of a prototype to confirm performance in a laboratory environment.

Phase II: Conduct a field trial of no less than five prototype devices to enhance the performance of biomass cookstoves in Kenya. In coordination with CDC representatives in Kenya, tests will be conducted to evaluate the performance of cookstoves with and without the stove enhancing prototypes. The goal is to confirm $\geq 85\%$ reduction in emissions as compared to the traditional three-stone fire.

Phase III: Conduct reliability testing for critical components of the prototype device to confirm successful operation for over 5000 hours of typical field use. In addition to accelerated laboratory evaluation of reliability, this program will expand the Kenya field trial to 30 devices. The safety of the cookstove with an enhancement component will be assessed.

Impact and Commercialization Potential: The expected results will help identify a technology that can be disseminated in Kenya households through using social marketing approach, that will reduce exposures to indoor air pollution, and improve health outcomes. This proposal addresses the following CDC public health priorities: 1) Increase global health impact; 2) Better prevent illness, injury, disability and death. We will approach this new technology commercialization through a variety of approaches, including commercial spin-off companies and technology licensing.

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NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH (NIOSH)

For additional information about NIOSH, please visit their web site at:

<http://www.cdc.gov/niosh/programs>.

High Risk Industrial Sectors in NIOSH

Exposure assessment, engineering controls, and personal protective technologies (PPT) are needed to manage exposures to occupational hazards in high risk industrial sectors. These include manufacturing, services, mining, agriculture and construction sectors. Workers in the **manufacturing sector**, comprising an estimated 14 million paid workers in 2005, face risks that include machinery, repetitive motion, overexertion, chemicals, nanomaterials, noise and shift work. In the **services sector**, work environments vary widely and these varied, and often uncontrolled, environments may put the estimated more than 65 million workers at risk of workplace injury, illness and death. The **mining sector**, comprised of over 300,000 paid workers in 2005 (not counting those in the oil and gas extraction sub-sector), face risks that include falling materials, explosions, fires, powered haulage, overexertion, electrical equipment, and exposure to particulates and dusts including diesel emissions, coal dust and silica dust. **Agriculture** ranks among the most hazardous industries. Farmers are at high risk for fatal and nonfatal injuries, work-related lung diseases, noise-induced hearing loss, skin diseases, and certain cancers associated with chemical use and prolonged sun exposure. Farming is one of the few industries in which the families (who often share the work and live on the premises) are also at risk for injuries, illness, and death. Each day, **construction workers** face injury hazards from falls, machines, electricity, motor vehicles, and other equipment and circumstances. Health hazards posed by construction work can include dusts, fumes, noise, and chemicals. Research is needed to develop control strategies, PPT, exposure assessment methods and interventions to reduce motor vehicle injuries and deaths in all these high risk industrial sectors.

The following research areas are of particular interest to NIOSH:

1. Control Technology and Personal Protective Equipment for High Risk Occupations

Background: Personal protective equipment (PPE) protects workers from death and disabling injuries and illnesses as well as from the specific threats of exposures to certain airborne biological particles, chemical agents, nanomaterials, splashes, noise exposures, fall hazards, head hazards, and fires. It is estimated that 20 million workers use PPE on a regular basis to protect them from job hazards and a total of 135,000 workers potentially could benefit from the use of PPE ([Worker Health Chartbook 2004](#)). Engineering controls include substitution of a safe material for a hazardous one, design changes to equipment, or modification of work methods to eliminate or reduce hazards. Research is needed to develop and evaluate control strategies and personal protective equipment for specific hazards and to assure their practicality and usability in workplaces in all the high risk industrial sectors.

For additional information about NIOSH PPE and Engineering control programs, please visit their web site at: <http://www.cdc.gov/niosh/programs/ppt/> & <http://www.cdc.gov/niosh/programs/eng/>.

Examples of specific research areas of interest include, but are not limited to:

- Conduct research on the ability of existing containment and control strategies to prevent releases and potential human exposures to engineered nanomaterials.
- Conduct research to evaluate the effectiveness of personal protective equipment (PPE) in protecting workers against exposure to engineered nanomaterials. Provide data to fill knowledge gaps and support guidance for the selection and use of gloves and protective garments to

prevent exposures. Respiratory protection research needs to be extended to a broad range of engineered nanomaterials.

- Develop a heads-up display coupled with a personal noise exposure monitoring system. Personal noise alert “badges” and personal noise dosimeters exist, but do not have an effective way to alert the user immediately when a noise hazard occurs. A system that displays a warning within the user’s visual field (via lights on protective eyewear, hardhat, etc.) would facilitate hazard recognition.
- Develop an inexpensive hand-held earplug test device based on the NIOSH QuickFit concept. Studies of hearing protector users have shown repeatedly that average protection values are much lower than the labeled Noise Reduction Ratings (NRR) determined in laboratories. A QuickFit test system would help workers determine if their hearing protection is giving them at least 15 decibels of attenuation.
- Develop innovative engineering control approaches and technologies for reducing asphalt exposures in roofing, and skin exposures and disease in construction workers.
- Conduct research to understand PPE integration and interoperability issues. In most cases, individual PPE are currently used without consideration for their ability to function together. Research is needed to test interfaces among different PPT and components. Current interfaces do not provide seamless integration of PPT components resulting in reduced comfort, fit, usability, and protection for the wearer as well as logistical challenges for safety managers and employers.
- Develop innovative educational and professional training materials suitable for today’s diverse workplace on the role of PPT in occupational safety and health. This is especially critical for high risk occupations. Innovative methodologies including social media should be explored and evaluated to demonstrate their effectiveness at improving workplace safety and health. For example, to what extent can mobile application media be focused on worker safety and health to provide up-to-date PPT information to a diverse range of employers and employees’ through portable communication devices?

Impact and Commercialization Potential: The impact of the proposed research will prevent work-related injury, illness, and death by advancing the state of knowledge and application of personal protective technologies (PPT). Potential products include technical methods, processes, techniques, tools, and materials that support the development and use of personal protective equipment worn by individuals to reduce the effects of their exposure to a hazard. NIOSH will continue its collaborative efforts in partnership with labor, industry, government, and other stakeholders.

2. Exposure Assessment Methods for High Risk Occupations

Background: Exposure assessment provides multi-disciplinary strategies and methods to anticipate, recognize, evaluate, control, and confirm effective management of occupational health stressors, exposures to those stressors, and resulting health risks. Major gaps in current approaches include: (1) the lack of practical methods for hazard identification and measurement that can be applied at reasonable cost in many workplaces where health stressors may exist, (2) the lack of validated, noninvasive biological methods for monitoring relevant exposure and resulting dose, and (3) the lack of strategies and methods for epidemiologic studies to demonstrate either a dose-response effect or a conclusion of no association between the agent and disease in the complex environments of today’s workplaces.

For additional information about NIOSH Exposure Assessment programs, please visit their web site at: <http://www.cdc.gov/niosh/programs/expal/>.

Examples of specific research areas of interest include, but are not limited to:

- As the rapidly emerging new approach to material science, two areas of research are needed to support effective assessment of worker exposure to engineered nanomaterials. 1. Real-time sensors capable of reliably detecting nanoparticles and providing information on size distribution

and count, and that can be used for personal monitoring; and 2. Development of methods that can detect and quantify the presence of engineered nanomaterials in samples collected for the purpose of characterizing exposures. These methods need to be cost-effective and available to the OS&H practitioner community. Broader application to general public health assessments should be factored into the research.

- Develop new or improved methods to measure occupational health stressors such as psychological and ergonomic factors, noise, chemicals, particles and fibers, physical agents, non-ionizing radiation, or mixtures of stressors in the work environment. Enhanced measurement performance and functionality can include sensitivity, selectivity, size and weight considerations, ease of use, and capabilities to measure multiple analytes simultaneously.
- Develop or adapt easy-to-use, direct-reading instruments and test kits to rapidly and inexpensively measure exposures in a variety of workplaces. Critical applications include routine monitoring, evaluating the success of control technologies, and supporting epidemiological studies. For example develop a sound level meter to monitor worker noise exposure that can be used in underground coal mines.
- Improve the measurement of low concentrations of chemicals and biomarkers in biological specimens such as blood, urine, saliva and sweat so that such concentrations can be linked to internal dose at the target organs, work tasks and workers can be categorized according to hazard bands and exposure bands, and at-risk workers can be identified and protected.

Impact and Commercialization Potential: This research will lead to the development of practical solutions and prevention activities to address complex problems that cause occupational diseases, injuries, and fatalities and that will lead to reductions in occupational injuries and illnesses among all workers. NIOSH is committed to building and maintaining collaborative partnerships with international organizations in labor, industry, and government, as well as with other interested stakeholders. Research to Practice (r2p): This research will lead to the development and translation of exposure assessment methods and research findings into prevention practices and products that will be adopted in occupational settings.

3. Occupational Traumatic Injuries from Motor Vehicle Crashes and Incidents

Background: The risk of roadway crashes and incidents associated with on-the-job operation of motor vehicles affects millions of U.S. workers. Motor vehicle-related incidents are consistently the leading cause of work-related fatalities in the United States. Of approximately 5,700 fatalities annually reported by the Bureau of Labor Statistics, 35% are associated with motor vehicles.

The public health toll from 2002 to 2008 included:

- 1354 workers died each year from crashes on public highways
- 324 workers died each year in crashes that occurred off the highway or on industrial premises.
- 358 pedestrian workers died each year as a result of being struck by a motor vehicle.

High-risk exposures include emergency response, highway construction zones, operation of farm equipment on roads, and off the highway use of commercial vehicles.

An important goal of the NIOSH Traumatic Injury Program is the reduction of injuries and fatalities due to highway motor vehicle crashes and incidents.

Examples of specific research areas of interest include, but are not limited to:

An important priority is the development of innovations to apply evidence-based interventions for occupational occurrences of motor vehicle crashes and incidents. Priorities include developing new design concepts and standards that may be used by national standardization groups to update or develop design standards for specific motor vehicles, enhancing effective interventions for driver education and

behavior to reduce motor vehicle incidents and crashes among professional drivers, evaluating intervention strategies for their effectiveness in reducing the number or severity work-related motor vehicle incidents and crashes, and enhancing engineering controls for the prevention of crashes and incidents or reducing the severity of traumatic injury associated with such crashes and incidents.

Public Health Impact: Application of evidence-based interventions may have a large impact on reducing the incidence occupational motor vehicle crashes and incidents. Workers sustaining fatal or serious injuries represent a huge toll on future years of productive life. In addition, their families are adversely affected. Any reduction in occurrence will have tremendous public health importance. In addition, reductions in occurrence will also have beneficial impacts on reducing workers' compensation and health insurance premiums and improving the productivity of American businesses. Given the extremely short induction period between exposure and injury occurrence, CDC can make a measurable difference in a very short period of time (< 4 years).

Visit the NIOSH homepage for more information on NIOSH's research program areas
<http://www.cdc.gov/niosh/homepage.html>.

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FOOD AND DRUG ADMINISTRATION (FDA)

FDA will accept SBIR grant applications on the April 5, August 5, and December 5, 2012 submission dates.

The FDA is responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation. The FDA is also responsible for advancing the public health by helping to speed innovations that make medicines and foods more effective, safer, and more affordable; and helping the public get accurate, science-based information they need to use medicines and foods to improve their health.

For additional information about areas of interest to the FDA, please visit our home page at
<http://www.fda.gov>.

CENTER FOR BIOLOGICS EVALUATION AND RESEARCH (CBER)

CBER is responsible for ensuring the safety, efficacy, potency and purity of biological and related products intended for use in the treatment, prevention or cure of diseases in humans as well as the safety of the nation's supply of blood and blood products. The primary responsibility of CBER is to review the quality, safety and efficacy of vaccines, blood products, certain diagnostic products and other biological and biotechnology-derived human products.

CBER's activities include: evaluating the quality, safety and effectiveness of biological products before marketing, and monitoring the pre-clinical and clinical testing of new biological products; licensing biological products and manufacturing establishments, including plasmapheresis centers, blood banks, vaccine and biotechnology manufacturers; AIDS program and policy activities, including research on AIDS therapeutic products, diagnostic tests and vaccines; research to establish product standards, develop improved testing methods and assess the safety of biological products; compliance, lot release program and post market surveillance; meeting PDUFA goals, new research programs, and new regulatory initiatives (managed review process for all products).

CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)

CDER develops FDA policy with regard to the safety, effectiveness, and labeling of all drugs for human use; evaluates new drug applications and investigational new drug applications; develops standards for the safety and effectiveness of all over-the-counter drugs; monitors the quality of marketed drugs through product testing (bioavailability/bioequivalence testing), post marketing surveillance, and compliance programs; develops guidelines on good manufacturing practices; conducts research and develops scientific standards on composition, quality, safety, and efficacy of human drugs.

Drug regulatory research as conducted in CDER is directed at the discovery of new knowledge relevant to drug development, post marketing drug experience (patterns of drug use and safety), and drug regulation to enhance FDA regulatory decisions. These drug regulatory decisions impact on the development of regulations, guidelines and guidance for the regulated industry and provide clarity and consistency in application of CDER regulatory requirements. These drug regulatory decisions also impact public health by ensuring that marketing drugs are safe and efficacious and that their risk: benefit profile remains acceptable during the market life of a drug. Specific areas of research conducted by the Center include: Pharmacology/toxicology, microbiology/virology, clinical pharmacology, pediatric issues in drug therapy, post marketing drug safety, evaluation of effectiveness of regulatory actions, patterns of drug use, including off-label, signal detection methodologies (e.g., data mining techniques), epidemiologic studies of therapeutics using population-based data, regulatory compliance, product quality, and active surveillance methods.

Research and development opportunities within the FDA that lend themselves to performance by small businesses include, but are not limited to, the following:

- A. Develop a system for gathering real-time data on physician prescribing behavior, understanding and compliance with drug product labeling and frequency of off-label prescribing.
- B. Develop and evaluate the effectiveness of new methods and tools for managing the known risks of marketed drug products (e.g., communicating newly identified risks to health care practitioners and patients).
- C. Develop methods for timely active surveillance of newly approved drug products in large populations to identify both expected and unexpected outcomes.
- D. Develop methods for actively collecting information on all cases of classically drug-associated events (e.g., acute liver failure, blood dyscrasias, severe desquamating skin disorders) to augment the FDA's current passive surveillance system.

- E. Develop improved clinical markers and methods with potential for bed-side application for detection of the early onset of adverse drug events.
- F. Develop surrogate potency methods for biotech drug products to replace traditional animal testing.
- G. Development of psychochemical and in-vitro biological tests to evaluate pharmaceutical equivalence of complex drug substances and drug products.
- H. Research into approaches to handle informative missing patient data in clinical trials, including innovations in study designs and statistical methods of analysis.
- I. Statistical and computational methods and strategies for the design, analysis and interpretation of microarray, genomic and proteomic data.

CENTER FOR FOOD SAFETY AND APPLIED NUTRITION (CFSAN)

The FDA is responsible for the safety of the vast range of food Americans eat; about 80 percent of all food sold in the United States. This includes everything except for the meat, poultry, and processed egg products that are regulated by the USDA. Consequently CFSAN seeks research designed to complement and accelerate efforts aimed at the detection, prevention, and control of contamination that may be responsible for illness or injury conveyed by foods, colors, and cosmetics. CFSAN conducts research, and develops regulations, guidance and standards related to the composition, quality, nutrition, and safety of food, food additives, colors, and cosmetics. The Center evaluates FDA's surveillance and compliance programs relating to foods, colors, and cosmetics; reviews industry petitions, and develops regulations for food standards to permit the safe use of color and food additives.

CFSAN maintains an active research program that is focused on the following priorities; ensuring the safety of food, dietary supplements and cosmetics; improving nutrition; and promoting the security and integrity of the food supply. The Center's research activities are intended to; support the FDA's regulatory activities; reduce the incidence of foodborne illness by improving our ability to detect and quantify foodborne pathogens, toxins, and chemicals that could jeopardize the safety and security of the food supply; find new and improved ways to control these agents; and safely produce, process, and handle food and food products. FDA is committed to reducing the incidence of foodborne illness to the greatest extent feasible while at the same time protecting the nation's food supply. Mission-critical knowledge gaps are addressed through translation research focused on the risks associated with FDA regulated products throughout their life cycles, from production to consumption. Ideally extramural research is sought that complements the Center's intramural research efforts, and which will enhance the Agency's and the Nation's ability to reduce the incidence of foodborne illness and protect the integrity of the nation's food supply. FDA's mission-critical needs require that the research not simply end with the generation of new knowledge and technologies, but extend to the validation of new approaches by using realistic conditions that accurately reflect the diversity of the food industry and offer potential solutions that can be accept by appropriate sectors of the food industry.

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH (CDRH)

CDRH develops FDA policy and solves problems related to public health and safety of medical devices and radiation-emitting electronic products. It evaluates applications for premarket approval of medical devices, approves products development protocols and exemption requests for investigational devices. It classifies devices into regulatory categories, develops safety effectiveness standards and good manufacturing practices regulations, operates post market surveillance and compliance programs, and provides technical, non-financial assistance to small manufacturers. The Center also conducts programs to reduce human exposure to hazardous ionizing and nonionizing radiation, through an electronic product radiation control program and other programs designed to control and limit radiation exposure. The Center develops and conducts research and testing programs in the areas of physical, life, and engineering sciences related to the human health effects of radiation and medical device technologies,

provides expertise and analyses for health-risk assessments, and also develops new or improved measurement methods, techniques, instruments and analytical procedures for evaluating product performance and reliability.

Research and development opportunities within the FDA that lend themselves to performance by small businesses include, but are not limited to, the following:

- A. Examine the setup, documentation and optimization of our Sun Grid Engine (SGE). The architecture of this networking application is particularly suited to managing surge capacity in high performance computing. The modeling of many physiologic functions and bioinformatic analyses can take months or even years to run on a standard desktop computer. The SGE takes the overall problem and distributes it to a cloud of computers on a network so that no user knows, or cares, if a computation is performing in the background on their machine. As FDA rolls out laptops with multi-core CPU's and which are equipped with prodigious amounts memory this experiment in "cloud computing" could become a reality on the Whiteoak Campus. The scope of work would be to develop, document, and provide training systems for developers, network architects, and users on working methodologies for the integration of cloud computing with the existing FISMA compliant conventional networking.
- B. Develop a high-speed, low light spectral CMOS linear imaging system to measure complete spectra of multiple variables from living tissue. Complete spectra of fluorescence signals (including auto-fluorescence and FRET) could be measured along a line at high speeds (10 kHz) with a rectangular CMOS grid (e.g. 10 x 1,000 pixels -> 10 sites 1000 wavelengths).
- C. Develop bioassays/biosensors to identify injurious levels of nerve stimulation utilizing bioluminescence and neurotransmitter detection technologies. Research capabilities needed include voltage clamp, current clamp and extracellular techniques in peripheral nerves and brain slices to explore stimulation protocols that release neuroactive substances released in injury and inflammation which are not normally evoked under normal physiological conditions.
- D. Design, build, and validate a phantom that is traceable to a national metrology institute (NMI) such as NIST (or any other NMI) to improve the accuracy and clinical utility of bone mineral density measurements made using dual energy X-ray absorptiometry (DXA). The calibration phantom should be constructed using biosurrogate materials with known/tabulated data for body tissue and tissue substitutes.

CENTER FOR VETERINARY MEDICINE (CVM)

CVM is a public health organization that enables the marketing of effective drugs, food additives, feed ingredients, and animal devices that are safe to animals, humans, and the environment. The Center, in partnership with Federal and state agencies and other customers, ensures animal health and the safety of food derived from animals. The Center makes timely, quality decisions and takes regulatory actions to ensure that these products provide for quality health care of animals, minimize the transmission of zoonotic diseases, and increase the efficiency of production of animal-derived food and fiber. Regulatory decisions are supported by research, the monitoring of product safety, and efficacy, and the continual improvement of processes.

Research and development opportunities within the Center for Veterinary Medicine that lend themselves to performance by small businesses include, but are not limited to, the following areas of interest:

- A. Development, for the specific purpose of obtaining approval or conditional approval, of products for the treatment, control or prevention of diseases or conditions occurring in minor species or small numbers of major species.
- B. Development and validation of high throughput/screening quantitative and qualitative analytical methods for analyzing drugs, additives, and contaminants in animal tissues and feeds.

- C. Development of methods to determine absorption, distribution, metabolism, and excretion of drugs, feed additives and contaminants (microbial and chemical) in food animals, including minor species.
- D. Development of new biomarkers and models for determining the safety and effectiveness of veterinary drugs and food additives in domestic animals, including minor species.
- E. Development of methods to determine the effects of drugs, food additives, and contaminants (microbial and chemical) on immunological and physiological functions of domestic animals, including minor species.

OFFICE OF CRITICAL PATH PROGRAMS

The Office of Critical Path Programs, in FDA's Office of the Chief Scientist, coordinates the cross-agency Critical Path Initiative (CPI), FDA's strategy for transforming the way medical products are developed, evaluated, and manufactured. CPI activities are under way throughout the Agency, from the product centers to the Office of the Commissioner. For details, see <http://www.fda.gov/ScienceResearch/SpecialTopics/CriticalPathInitiative/default.htm>. Collaboration is key to the CPI initiative because bringing safe, effective, and innovative therapies to the American public requires FDA to leverage the resources and expertise of all stakeholders, including other Federal agencies, academia, healthcare professionals, patient and consumer groups, regulated industry, and health-related organizations. In 2008, CPI collaborations involved 84 government agencies, universities, industry leaders, and patient groups from 28 states and 5 countries on a raft of groundbreaking research projects.

Research and development opportunities within FDA that lend themselves to performance by grantees include, but are not limited to, the following:

- A. Studying the immunological correlates of TB immunity and developing tools to evaluate TB vaccine efficacy
- B. Developing study models for testing combination-antimicrobials as a strategy to prevent the development of drug resistance
- C. Developing new approaches to preclinical safety testing
- D. Identifying biomarkers for safety and efficacy evaluation of medical products

OFFICE OF ORPHAN PRODUCTS DEVELOPMENT

The Office of Orphan Products Development was established to identify and facilitate the development of orphan products. Orphan products are drugs, biologics, medical devices and foods for medical purposes, which are indicated for a rare disease or condition (i.e., one affecting fewer than 200,000 people in the United States). These products may be useful in a rare disease/disorder but lack commercial sponsorship because they are not considered commercially attractive for marketing. A subcategory of orphan products are those marketed products in which there is evidence suggesting usefulness in a rare disease/disorder but which are not labeled for that disease/disorder because substantial evidence of safety and effectiveness for that use is lacking.

Research and development opportunities within the FDA that lend themselves to performance by small businesses include, but are not limited to, the following:

- A. Development of products for the treatment of rare diseases or disorders including but not limited to neurological, metabolic, genetic, ophthalmologic, hematologic, and dermatological diseases or disorders for the specific purpose of obtaining marketing licensure.

- B. Development of products for use in diagnosis of rare diseases for which the diagnostic tool would be used in fewer than 200,000 persons annually in the United States.
- C. Development of vaccines for the prevention of rare diseases to be used in fewer than 200,000 persons annually in the United States.

Other Research Topic(s) Within the Mission of FDA

For additional information on research topics and administrative and business information, contact:

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Food and Drug Administration
Division of Acquisition Support and Grants
5630 Fishers Lane - HFA 500
Rockville, MD 20857

ADMINISTRATION FOR CHILDREN AND FAMILIES

The Administration for Children and Families (ACF), within the Department of Health and Human Services (HHS) is responsible for federal programs that promote the economic and social well-being of families, children, individuals, and communities. ACF partners with State and local governments, for-profit and non-profit organizations, faith- and community-based organizations, American Indian Tribes and Native American communities to design, administer and promote programs in areas such as child welfare, childcare, Head Start, healthy marriage, Temporary Assistance for Needy Families (TANF), and responsible fatherhood.

The Office of Planning, Research and Evaluation (OPRE) facilitates ACF's SBIR investments. The Office provides guidance, analysis, technical assistance, and oversight to ACF programs on strategic planning aimed at measurable results; research and evaluation methodologies; demonstration testing and model development; statistical, policy and program analysis; synthesis and dissemination of research and demonstration findings.

The focus of the research topics for SBIR should reflect the research and programmatic interests of ACF. Particular areas of interest for ACF include but are not limited to:

- Adoption and Foster Care
- Child Abuse & Neglect
- Child Care
- Child Support
- Developmental Disabilities
- Early Head Start
- Energy Assistance
- Family/Domestic Violence
- Fatherhood and Healthy Marriage
- Head Start
- Native American and Tribal Programs
- Refugee Resettlement
- Human Trafficking
- Temporary Assistance for Needy Families
- Youth Development

For additional information on ACF programs and research, please visit the ACF web site at <http://www.acf.hhs.gov> and the Office of Planning, Research and Evaluation's web site at <http://www.acf.hhs.gov/programs/opre/index.html>.

For additional information on research topics, contact:

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