

Community Participation in Research

270 DP 12035

PA Number: PAR-05-026 (Two additional participants added, see NOT-OD-05-017 and Research objectives of NIDCD added, see NOT-OD-05-018)

Part I Overview Information

Department of Health and Human Services

Participating Organizations

National Institutes of Health (NIH), (<http://www.nih.gov>)
Agency for Healthcare Quality and Research (AHRQ), (<http://www.ahrq.gov>)
Centers for Disease Control and Prevention (CDC), (<http://www.cdc.gov>)

ACCOUNT
AHRQ

Components of Participating Organizations

Office of Behavioral and Social Sciences Research (OBSSR), (<http://obssr.od.nih.gov>)
National Cancer Institute (NCI), (<http://www.nci.nih.gov>)
National Heart, Lung, and Blood Institute (NHLBI), (<http://www.nhlbi.nih.gov>)
National Institute of Child Health and Human Development (NICHD), (<http://www.nichd.nih.gov>)
National Institute of Dental and Craniofacial Research (NIDCR), (<http://www.nidcr.nih.gov>)
National Institute of Environmental Health Sciences (NIEHS), (<http://www.niehs.nih.gov>)
~~National Institute of Nursing Research (NINR), (<http://ninr.nih.gov/ninr/>)~~
National Institute on Alcohol Abuse and Alcoholism (NIAAA), (<http://www.niaaa.nih.gov>)
National Institute of Mental Health (NIMH), (<http://www.nimh.nih.gov>)
National Institute on Deafness and Other Communication Disorders (NIDCD), (<http://www.nidcd.nih.gov>)
Agency for Healthcare Research and Quality (AHRQ), (<http://www.ahrq.gov>)
National Institute for Occupational Safety and Health (NIOSH), (<http://www.cdc.gov/niosh/homepage.html>)

Announcement Type

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Training members
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Mexico -
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Executive Summary

- The ultimate goal of this PAR is to support research on health promotion, disease prevention, and health disparities that is jointly conducted by communities and researchers.
- This PAR invites NIH research project grant (R01) and exploratory/developmental grant (R21) award mechanisms.
- The total amount to be awarded depends on the scientific merit of applications and the funds available at the participating NIH Institutes/Centers.
- The anticipated number of awards is contingent on their scientific merit and the funds available in the general funding pool of the participating NIH Institutes/Centers.
- Eligible organizations include for-profit and not-for-profit, public or private organizations, units of state and local

governments, eligible agencies of the Federal Government, domestic or foreign institutions/organizations, faith-based or community-based organizations, and Native American tribal organizations.

- Eligible principal investigators are any individuals with the skills, knowledge, and resources necessary to carry out the proposed research.
- The number of applications each applicant may submit is unrestricted.
- The PHS 398 application instructions are available at <http://grants.nih.gov/grants/funding/phs398/phs398.html> in an interactive format. For further assistance contact GrantsInfo, Telephone (301) 435-0714, Email: GrantsInfo@nih.gov.

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Part II - Full Text of Announcement

Section I. Funding Opportunity Description

1. Research Objectives

The goal of this PAR is to support research on health promotion, disease prevention, and health disparities that is jointly conducted by communities and researchers. This PAR invites NIH research project grant (R01) and exploratory/developmental grant (R21) award mechanisms.

Community-based participatory research (CBPR) is defined as scientific inquiry conducted in communities and in partnership with researchers. The process of scientific inquiry is such that community members, persons affected by the health condition, disability or issue under study, or other key stakeholders in the community's health have the opportunity to be full participants in each phase of the work (from conception - design - conduct - analysis - interpretation - conclusions - communication of results). CBPR is characterized by substantial community input in the development of the grant application (<http://www.niehs.nih.gov/translat/cbpr/cbpr.htm>).

Community-partnered approaches to research promise to deepen our scientific base of knowledge in the areas of health promotion, disease prevention, and health disparities. Community-partnered research processes offer the potential to generate better-informed hypotheses, develop more effective interventions, and enhance the translation of the research results into practice. Specifically, involving community and academic partners as research collaborators may improve the quality and impact of research by:

- More effectively focusing the research questions on health issues of greatest relevance to the communities at highest risk;
- Enhancing recruitment and retention efforts by increasing community buy-in and trust;
- Enhancing the reliability and validity of measurement instruments (particularly survey) through in-depth and honest feedback during pre-testing;
- Improving data collection through increased response rates and decreased social desirability response patterns;
- Increasing relevance of intervention approaches and thus likelihood for success;
- Targeting interventions to the identified needs of community members
- Developing intervention strategies that incorporate community norms and values into scientifically valid approaches;
- Increasing accurate and culturally sensitive interpretation of findings;
- Facilitating more effective dissemination of research findings to impact public health and policy;
- Increasing the potential for translation of evidence-based research into sustainable community change that can be disseminated more broadly.

TRAD MOD

For the purpose of this PAR, community refers to populations that may be defined by: geography; race; ethnicity; gender; sexual orientation; disability, illness, or other health condition; or to groups that have a common interest or cause, such as health or service agencies and organizations, health care or public health practitioners or providers, policy makers, or lay public groups with public health concerns. Community-based organizations refer to organizations that may be involved in the research process as members or representatives of the community. While not an exhaustive list, organizations as varied as Tribal governments and colleges, state or local governments, independent living centers, other educational institutions such as junior colleges, advocacy organizations, health delivery organizations (e.g., hospitals), health professional associations, non-governmental organizations, and federally qualified health centers are possible community partners.

Additional Resources

- Community Based Participatory Research: Assessing the Evidence (2004). Vishwanathan, M et. al., Editors. Agency for Healthcare Research and Quality: Rockville, MD.
- Community Based Participatory Research for Health. Meredith Minkler & Nina Wallerstein (Editors). Jossey Bass, San

Francisco, 2003.

Successful Models of Community Based Participatory Research (2000). O'Fallon, L, Tyson, F, and Dearry, A. (Editors). National Institute of Environmental health Sciences: Research Triangle Park, NC.

Institute of Medicine (2000). *Promoting Health Intervention Strategies from Social and Behavioral Research*. Smedley, B.D. & Syme, L., Editors. National Academy Press: Washington DC.

Research Objectives

Several institutes and offices within NIH, CDC and AHRQ have joined together to support this initiative. Applications should be relevant to both the objectives of the PAR and to at least one of the participating organization's general research interests. Researchers are strongly encouraged to both review the general research interests of the participating institutes supporting this announcement and to review the examples of topics of interest specific to CBPR (shown below). As additional research areas are welcome, prospective applicants are encouraged to contact the relevant program administrator for this CBPR PAR as listed in the INQUIRES section of this announcement prior to preparing an application. While not an exhaustive list, CBPR projects focused on the following areas of health promotion, ~~disease prevention~~ and health disparities are encouraged:

Agency for Healthcare Research and Quality

Disabilities

In accordance with the goals of the New Freedom Initiative, AHRQ, <http://www.ahrq.gov/>, is interested in community-based participatory research efforts targeted towards increasing health promotion and prevention of secondary conditions in persons with disabilities through community-partnered evaluation of supports and access, and developing or assessing strategies to improve quality of care and reduce disparities for persons with disabilities.

Persons with disabilities are individuals that have limitations in major life activities. Secondary conditions may be multi-dimensional, and include non-medical events (i.e. isolation); conditions that affect the general population (i.e. obesity); and problems that arise at any time during the lifespan, (i.e. inaccessible examination equipment) (CDC, 2003). Community-based research partnerships with disability advocacy groups offer the opportunity to address the self-identified priorities of persons with disabilities; examine access to services and facilities; develop and test patient-centered approaches; or adapt evidence-based or prevention strategies to meet the needs of persons with disabilities.

Research proposals may include examination of:

- Effectiveness of prevention guidelines or strategies in decreasing risk behaviors and promoting health of persons with disabilities;
- Utilization of consumer assessment of health plans by persons with disabilities to improve the quality of health care delivery;
- Use of community "built" environment checklists to effectively identify barriers and supports to health care facilities and services to persons with disabilities;
- Identification of training needs of providers in community-based service provision for persons with disabilities;
- Approaches to the reduction of disparities among racial, ethnic, and socioeconomic subgroups of persons with disabilities; or
- Opportunities to identify factors that assist in explaining under utilization or over utilization of community-based services by persons with disabilities.

National Cancer Institute

DHHS recently announced a trans-HHS report entitled: "Making Cancer Health Disparities History" (<http://www.chdprg.omhrc.gov/>). In this report, a broad coalition of scientists, practitioners, community and patient advocates organized by the NCI, <http://www.nci.nih.gov/>, identified several research themes that would best be addressed through a CBPR model. These include but are not limited to:

- The need for more cancer prevention and health promotion (e.g., tobacco control, diet/physical activity to reduce obesity) research in medically underserved populations such as racial/ethnic minorities, and low SES populations (e.g., rural poor).
- Cancer prevention and health promotion research should integrate scientific questions related to

intergenerational differences, lifespan, mental health and emotional well-being.

- Studies that develop standards and test models for ensuring cultural competence in the delivery of prevention, early detection, treatment and cancer survivorship services.
- Studies that identify and test strategies for overcoming the barriers (e.g., unequal service resource allocation, cost-effectiveness) to the adoption of evidence-based interventions in medically underserved communities.

Developing and testing models in medically underserved communities (e.g., patient navigation) to enhance access to and utilization of high quality cancer screening, diagnostic, treatment, and survivor support services.

National Institute for Occupational Safety and Health

The National Institute for Occupational Safety and Health (NIOSH), <http://www.cdc.gov/niosh/homepage.html>, is the federal agency responsible for conducting research and making recommendations for the prevention of work related injury and illness. NIOSH provides national leadership to prevent work-related illness and injury through research, education, training, and prevention/intervention. One of the National Occupational Research Agenda (NORA) priorities is Special Populations at Risk. These populations are defined as groups of workers who have (1) biological, social, or economic characteristics that place them at increased risk of developing work-related conditions and (2) inadequate information collected about them in the past. They may be disproportionately exposed to hazards and unusually vulnerable to exposures. And they may have less access to or lower quality of care after acquiring an illness or injury. These special populations include minority workers, female workers, younger and older workers, workers with medical or genetic susceptibility, workers with disabilities, immigrant workers, and migrant and agricultural workers. These populations are often employed in some of the most dangerous occupations including farming, mining, manufacturing, and day labor. Some work-related illnesses identified include silicosis, lead poisoning, musculoskeletal disorders, and pesticide-related illnesses. Many conferences and reviews have contributed to identifying the health and safety research needs of these unique or special populations at risk (National Occupational Research Agenda Update July, 1997; 1998). However, community involvement and contributions in identifying workplace injury and illness concerns has been limited.

In addition, there is an identified need for minority and underrepresented professionals who bring multi-cultural and multi-ethnic experiences to address the research needs of these specific worker populations. The NIOSH is committed to the support of programs designed to increase the number of underrepresented, minority, and female scientists participating in occupational health and safety research. Therefore, applications from under-represented individuals are encouraged to apply.

Types of research that may be proposed include, but are not limited to:

- Identify occupational jobs and conditions in which large disparities in risk, exposure, and prevention exist for various racial, ethnic, and gender groups, including approaches for detecting, diagnosing, preventing and treating occupational disease and injury.
- Translation of safety training research findings to identified special populations. Develop tools to translate health and safety research findings to underserved or underrepresented populations.
- Identification and perceptions by these populations of work organization risk factors to safety and health including development of appropriate interventions (protective equipment, training, and best work practices).
- Impact of work on the older workforce (psychosocial work environment, role of occupation in health disparities, employment barriers)
- Incidence of health outcomes in the underserved workforce, such as cardiovascular disease, obesity, cancer, mental health, and access to health care.

In addition to the preceding areas of emphasis, R21 research projects might be particularly suitable for addressing such issues as the following:

- Exploratory methodological studies: examination of the CBPR approach as an innovative methodology to use in a scientific area;
- The development and enhancement of the CBPR process (e.g. issues of consent, IRB processes, the development of new community-researcher partnerships, etc.), in epidemiological, prevention research, intervention research, or health services research.

- Add other general purposes for which the R21 application may be well-suited, such as getting partnerships off the ground.

Note: R01 applications can consider adding a component to address the above issues.

National Institute of Child Health and Human Development

NICHD, <http://www.nichd.nih.gov/>, is interested in research projects of child health and development that are community based, community level and/or community participatory. Studies are encouraged that examine:

- The interrelationship of socio-economic status and/or poverty with community factors on child health and development;
- The interrelation of community interactions as explanations of health disparities in children and young adults;
- The community's influence on children's understanding of health and illness and how that understanding relates (translates) to health behavior;
- The impact of community influences on the physiology of pregnancy and the infant in relation to health outcome;
- Community influences on fertility, maternal health during pregnancy, labor, delivery and postpartum periods, breast feeding patterns, and nurturing and rearing of infants and children by both parents- especially, fathers;
- The role of community with respect to health-related beliefs or attitudes on achieving and maintaining health and well-being of children and youth with physical, learning or developmental disabilities;
- Community influences on children with physical disabilities caused by injury and their adaptation to the impairments.

National Institute of Dental and Craniofacial Research

The U.S. Surgeon General's Report "Oral Health in America" acknowledges the consequential disparities in oral health status that exist within vulnerable populations and affects important aspects of quality of life including substantial pain, inability to chew and diminished social interaction. Increasingly oral health is associated with systemic health including low 5- year survival for those with oral and pharyngeal cancer, the relationship between tooth loss and nutritional outcomes, and the bi-directional relationship between periodontal disease and diabetes. Racial and ethnic minorities, the poor, those with acquired or developmental disabilities, the immunocompromised and frail and dependent elders often suffer the worst oral health. The Report is emphatic that to improve quality of life and eliminate oral health disparities health professionals, individuals and communities must work together. The National Institute of Dental and Craniofacial Research's, (<http://www.nidcr.nih.gov/>), *Plan to Eliminate Craniofacial, Oral and Dental Health Disparities* focuses the research community's attention on oral infectious diseases (Early Childhood Caries, coronal caries, and periodontal diseases) and oral and pharyngeal cancer <http://www.nidcr.nih.gov/NR/rdonlyres/54B65018-D3FE-4459-86DD-AAA0AD51C82B/0/hdplan.pdf>.

Examples of the types of research that would be responsive to this program announcement include but are not limited to:

- Development of culturally appropriate methods for assessing determinants of oral health, oral health-related quality of life, and health outcomes in vulnerable populations.
- Epidemiologic studies designed to determine disease incidence and prevalence in vulnerable populations and simultaneously examine the broad array of potential determinants of oral health disparities.
- Studies that explore approaches to increase the recruitment and retention of women and minorities, those with disabilities and vulnerable populations in oral health clinical research.
- Development and testing of innovative approaches to address environmental, social, behavioral and biological determinants of disparities in oral health and oral health-related quality of life.
- Exploration of methods to improve dissemination and adoption/implementation of oral health-related prevention and health promotion strategies by a wide range of organizations, agencies, educational institutions, faith-based organizations, health care professionals, care givers, health advocates and influential others in the community.

Proposals involving a clinical trial design will not be considered responsive to this PAR for the NIDCR.

National Institute of Environmental Health Sciences

To help reduce the burden of environmentally associated diseases and health conditions, NIEHS, <http://www.niehs.nih.gov/>, promotes the use of the CBPR process to: 1) provide the scientific basis for understanding the impact of the environment on human health; 2) translate this information into prevention and intervention strategies; 3) evaluate the efficacy of prevention and intervention strategies; and 4) communicate the results to the public and improve public health. For further information on the CBPR Program at NIEHS, see: <http://www.niehs.nih.gov/translat/cbpr/cbpr.htm>. There are disproportionate sitings of hazardous waste facilities, landfills and manufacturing/industrial facilities in underserved or vulnerable communities (based on race, ethnicity, gender, immigration status and/or SES). In many of these communities, there are disparate outcomes from exposures based on individual susceptibility that may result in a variety of adverse health outcomes such as birth defects, premature birth, diabetes, cancer, cardiovascular, pulmonary, and auto-immune diseases. NIEHS encourages a broad, comprehensive approach to this problem that emphasizes both education and research. Examples of projects that would be considered responsive to this PAR include but are not limited to the following:

- Development of efficacious methods for risk and/or exposure assessment in low-income and underserved communities impacted by environmental hazards (including but not limited to chemical exposures, the built environment, etc).
- Develop innovative community based approaches to address environmental determinants (particularly the interaction between biological and environmental factors) of health disparities and health outcomes.
- Development of community-based, culturally sensitive research agendas to address environmental risks to mitigate adverse health effects from environmental exposures.

These community-based prevention/intervention research projects should expand our knowledge and understanding of the potential causes and remedies of environmentally related disorders, while at the same time enhancing the capacity of communities to participate in the processes that shape research approaches and intervention strategies. Projects are encouraged to include a comprehensive plan to have an ongoing evaluation from the inception of the project to its completion – including but not limited to an assessment of the partnership among various team members and policy and public health impact. It is highly recommended that proposals make recommendations for future activities, beyond the period of current funding, to assure continued participation of community members in research and service programs addressing environmental injustices.

For a partial list of areas of special interest to NIEHS please see the current Areas of Special Interest (<http://www.niehs.nih.gov/dert/programs/special/special.htm>) as detailed in the sections subtitled "Obesity and the Environment," "The Translation of Basic Biology to Clinical Studies and Environmental Medicine," and "Environmental Health and Biology of Aging."

National Institute of Nursing Research

The National Institute of Nursing Research (NINR) has a history of encouraging community-partnered research to promote health and to decrease health disparities. NINR's scientific program areas (<http://ninr.nih.gov/ninr/>) include neurofunction and sensory conditions, reproductive health and child health promotion, immune responses (including HIV/AIDS) and oncology, cardiopulmonary health, chronic illness management and end-of-life care. Developmental and intervention research in any of these areas that clearly incorporate communities as partners would be of interest to NINR. The following are potential examples of research related to this program announcement. These examples are not listed in any priority order and are not to be viewed as exhaustive or all-inclusive.

- Development and testing of culturally relevant measures of clinical and cost outcomes of community-partnered interventions aimed at reducing health disparities.
- Intervention studies designed to reduce risk factors and risk exposures that contribute to major areas of concern relevant to the NINR scientific program areas noted above (e.g., cardiovascular disease, diabetes, HIV/AIDS, cancer screening and management, infant mortality, or immunization).
- Intervention studies to enhance health seeking and health maintenance behaviors that incorporate the sociocultural attributes and cultural norms and values of communities and their members.

- Intervention studies devoted to preventing, reducing, or ameliorating health behaviors associated with such major contributors to morbidity and mortality as tobacco use, diet and activity patterns, interpersonal violence, or risky sexual behavior.
- Innovative intervention studies using technology to monitor and/ or facilitate the management of chronic illness among identified communities and their members.

National Institute on Alcohol Abuse and Alcoholism

The National Institute on Alcohol Abuse and Alcoholism (NIAAA), <http://www.niaaa.nih.gov/>, is interested in community participation in interventions to reduce heavy drinking and alcohol-related problems and promote healthy lifestyles in communities, especially where health disparities exist. Community-based participatory research has the potential to reduce development of alcohol use disorders, alcohol-related injuries and fatalities and delay or prevent underage drinking and alcohol-related problems such as violence, unplanned pregnancies, sexually transmitted diseases, and alcohol-related medical and psychiatric disorders. These are areas in which the active participation of both communities and researchers may enhance the development of innovative research approaches. Community involvement facilitates the development and testing of interventions in settings that are particularly relevant to health promotion as well as reducing health disparities. Research is also needed on the relative effectiveness and acceptability of different implementation strategies in diverse population groups.

Research is needed to develop and test community-level strategies that reduce alcohol-related problems and their consequences, including person-focused interventions and changes in alcohol policy, regulation, or pricing.

Interventions that can be transferred to other communities are especially important. Interventions should be acceptable to communities, feasible in terms of available economic and technical resources, and sustainable over time. Suggested strategies include, but are not limited to:

- Research that evaluates collaborative community-based interventions that combine the efforts of community, schools, family, media, and/or law enforcement to reduce or prevent underage access to alcohol.
- Research that develops and tests community-based primary and secondary prevention efforts to reduce risky behaviors such as driving after drinking and binge drinking.
- Research that investigates changes in alcohol price and/or availability, changes in alcohol-related laws and regulations, and the impact of these changes on underage access to alcohol, alcohol-related traffic injuries and fatalities, alcohol-related non-traffic injuries, and alcohol-related violence.
- Research that addresses the impact of access to alcohol prevention, early intervention and other treatment services on health promotion, disease prevention and the level of health disparities within communities.
- Research that studies the translation and dissemination of effective alcohol-reduction strategies and interventions from one community to another.



Research that specifically focuses on questions identified as crucial by discrete communities as defined by geography, culture, demographic commonality or shared interest.

National Heart, Lung, and Blood Institute

Increasing evidence demonstrates the important role of individual and community level behaviors in influencing the course of cardiovascular, lung, and blood diseases. To promote the development of innovative strategies for improving public health, the NHLBI, <http://www.nhlbi.nih.gov/>, encourages scientific research that includes the community of interest in the determination of the goals, design, implementation, and interpretation of the research. Research is needed not only to develop and evaluate new intervention strategies, but also to test the feasibility and effectiveness of community-based participatory approaches to the research endeavor. Examples of potential research topics that would be responsive to the NHLBI's interest in this PAR include, but are not limited to, the following:

- Evaluate methods to improve awareness and treatment of hypertension.
- Evaluate programs to encourage and sustain leisure-related exercise for cardiovascular fitness.
- Investigate interventions that address multiple risk factors for people at high risk for coronary artery disease.
- Evaluate interventions to improve effectiveness of physician/medical system patient encounters to identify and treat cardiovascular diseases or conditions.
- Develop and test innovative strategies to address how biological, genetic, or environmental factors may be used as biomarkers to screen for cardiovascular disease.

- Evaluate methods to improve the awareness and acceptability of the use of genetics and pharmacogenetics in the diagnosis and treatment of cardiovascular disease.
- X • Evaluate interventions to modify family environmental factors associated with obesogenic diet and sedentary behaviors.
- ✓ • Examine innovative models for enhancing access to, and appropriate utilization of health services among medically underserved communities (e.g. rural areas, low SES communities, American Indian and Alaska Native communities).
- ✓ • Evaluate methods to overcome barriers in the translation of clinical guidelines to patients and clinicians for obesity and prevention and treatment of hypertension in community settings.
 - Examine the use of CBPR approaches in large scale social marketing projects in diverse community that target environmental and societal changes to promote healthy weight levels.
- ✓ • Evaluate school based interventions to promote prevention and treatment of hypertension and/or obesity.
 - Examine the effectiveness of support groups for adults with sickle cell diseases in improving quality of life, coping skills, and health behaviors.
 - Examine the effectiveness of life skills training for adolescents with hereditary blood disorders.
 - Compare educational interventions to help children with hereditary blood disorders function at grade level and avoid poor school performance and failure.
 - Develop and evaluate community based pain management programs for adults with sickle cell disease.
 - Develop and evaluate donor recruitment programs for racial/ethnic groups that are underrepresented in blood and bone marrow donation programs.
- X • Evaluate the benefits of community based, system wide approaches to improving the asthma care available to and effectively used by patients at high risk of asthma morbidity (e.g. programs that link school/workplace, medical, and family/neighborhood efforts in the community).
- ✓ • Evaluate community center health workers, lay opinion leader, or other community centered interventions to improve families' management of a child's asthma.
 - Evaluate community systems approaches to improving physician adoption of asthma clinical practice guidelines.
- X • Evaluate the integration of asthma programs with community services for other chronic illness or public health programs to improve life-skills training (e.g. community recreational sports programs; parenting classes; after-school programs or early childhood education classes).

National Institute of Mental Health

The National Institute of Mental Health (NIMH), <http://www.nimh.nih.gov>, has a long history of concern and action related to health disparities and racial/ethnic populations as well as other underrepresented groups (i.e., women, children, disabled) for both its mental health and HIV/AIDS research agendas. Disparities research for mental health and HIV/AIDS outcomes takes into consideration relevant complex factors that influence disparities in services, particularly across special population groups, as well as women and children, and persons living in rural and frontier areas. A range of effective preventive interventions that can be transferred to the community must be implemented in view of the burden from unequal access to health care resources, disproportionate impact of comorbid conditions, and marginalization of subpopulations within these communities. Additionally, disparities in services research addresses care delivered in a variety of settings such as the specialty mental health sector, the general medical sector, and community settings (e.g., schools). Also, it supports research that examines innovative services interventions (e.g., community-based participatory methods, faith-based) to overcome disparities related to mental health and HIV service delivery and use.

Some types of research areas that may be proposed include, but are not limited to:

- Studies to address the reduction of disparities in services using multi-level interventions (e.g., organizational and community; interpersonal and socio-cultural).
- X • Use of community-based participatory research techniques to enhance the relevance of research questions and improve uptake of findings.
 - Adaptation of evidence- based practices to new settings and populations.
 - Development of research on how individual, socio-cultural, and organizational contexts affect access to, use of, and perceptions of mental health services for racial/ethnic populations with cross-disciplinary translational approaches.
 - Identification of factors that overcome health disparities relevant to health service delivery and use by ethnic minority populations to determine why there are disparities in access to and in the use of mental health and mental health related services within and across ethnic racial/ethnic populations. Also, determine the differential

patterns of mental health service utilization across racial/ethnic populations and majority populations.

- Dissemination of effective prevention interventions to racial and ethnic minority communities through community based organizations, providers of mental health and/or HIV-related care and services, and minority predominant and minority serving institutions.
- Projects to facilitate the establishment of research partnerships between minority institutions and the communities they serve by enhancing and expanding initiatives that support mental health and HIV-related research in minority communities.

Centers for Disease Control and Prevention. (2003). Secondary Conditions: Children and Adults with Disabilities. Available at: http://www.cdc.gov/ncbddd/factsheets/secondary_cond.pdf. Accessed April 29, 2003.

Section II. Award Information

1. Mechanism of Support

This funding opportunity will use the NIH research project grant (R01) exploratory/developmental grant (R21) award mechanisms. As an applicant, you will be solely responsible for planning, directing, and executing the proposed project.

The evolution and vitality of the biomedical, behavioral and clinical research requires a constant infusion of new ideas, techniques, and points of view. By using the R21 mechanism, the NIH seeks to foster the introduction of novel scientific ideas, techniques, models, tools, agents, targets, methodologies, technologies, and applications that have the potential to substantially advance biomedical, behavioral and clinical research on health-related topics. The R21 mechanism is intended to encourage new, exploratory and developmental research projects by providing support for the early stages of their development (i.e., in extending previous discoveries toward new directions or applications, etc.). Exploratory/developmental grant support is for new projects only; competing continuation applications will not be accepted. Applications for R21 awards should describe projects distinct from those supported through the traditional R01 mechanism. For example, long-term projects, or projects designed to increase knowledge in a well-established area will not be considered for R21 awards.

This funding opportunity uses just-in-time concepts. It also uses the modular as well as the non-modular budget formats (see <http://grants.nih.gov/grants/funding/modular/modular.htm>). Specifically, if you are submitting an application with direct costs in each year of \$250,000 or less, use the modular budget format described in the PHS 398 application instructions. Otherwise follow the instructions for non-modular research grant applications. All R01 applications should follow the instructions for non-modular budget research grant applications. This program does not require cost sharing as defined in the current NIH Grants Policy Statement at http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part2.htm.

R21 applications may request a project period of up to two years with a combined budget for direct costs of up to \$275,000 for the two-year period. For example, you may request \$100,000 in the first year and \$175,000 in the second year. The request should be tailored to the needs of your project. Normally, no more than \$200,000 may be requested in any single year.

2. Funds Available

Applications received in response to this program announcement will compete for funds in the general funding pool of the participating NIH ICs. No specific funds have been set aside for this announcement. The number and size of the awards will depend on the number of applications received, their relative scientific merit, and the general availability of funds for investigator-initiated research at the participating ICs.

Because the nature and scope of the proposed research will vary from application to application, it is anticipated that the size and duration of each award will also vary.

Section III. Eligibility Information

1. Eligible Applicants

1.A. Eligible Institutions

You may submit (an) application(s) if your organization has any of the following characteristics:

- For-profit or non-profit
- Public or private institutions, such as universities, colleges, hospitals, and laboratories
- Units of State and local governments
- Eligible agencies of the Federal government
- Domestic or foreign institutions/organizations
- Native-American tribal organizations
- Faith-based or community-based organizations

For instance, organizations as varied as Tribal governments and colleges, state or local governments, independent living centers, other educational institutions such as junior colleges, advocacy or research organizations, health delivery organizations (e.g., hospitals) and health professional associations are eligible institutions or possible community partners.

Applications from foreign institutions must conform to the NIH's policy for foreign grants. See http://grants.nih.gov/grants/policy/nihgps/part_iii_5.htm.

1.B. Eligible Individuals

Any individual with the skills, knowledge, and resources necessary to carry out the proposed research is invited to work with their institution to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for NIH programs.

2. Cost Sharing

Not required.

3. Other-Special Eligibility Criteria

- The investigators for each research proposal must define the relevant community or communities for their study using a set of tangible and explicit criteria. The criteria can include a common interest, identity, characteristic, or condition. They must also clearly identify who from that community will be included as participants in the research process. It is typically ideal in participatory research for the community in which the study is based to be involved in all or most phases of the research process. In some cases, however, it may not be possible for participants to be involved in all phases, or participants themselves may choose not to be involved in one or more phases. The absolute minimum involvement that can still be considered as participatory research is for participants to be involved at the front end of the study in helping to identify the research questions of most importance to the community, and then also at the back end in helping to interpret and apply the research findings to ensure that they maintain their relevance for the community. The investigators for each proposal must identify in which phases of the research community members are engaged as participants.
- Applicants must describe an existing or proposed involvement with one or more community-based organizations. This connection is essential to the development of community-based approaches and should also enhance the potential for long-term impact of the project. It is also essential that all facets of the project design be educationally and culturally appropriate, as well as appropriate to participants' ability. Letters of support from each partnering community, that describe the working relationships with the researcher, should be provided.
- The following two elements should also be considered in the 25 page limit for the R01 in applications submitted in response to this announcement.

- An Assessment Plan Identify the means of establishing effective input from a community on matters such as priority areas of health or plausible approaches and constraints in addressing health concerns. In addition to providing funding for the time and effort of the community partners who are serving as co-investigators on the project (including the cost of providing respite care for those projects focused on a disability community), applicants are encouraged to create a community-based advisory board or steering committee to facilitate planning, education, outreach, dissemination, and evaluation efforts. Input could be obtained directly from members of a community as well as from representatives of such groups as community and neighborhood associations, churches, public housing resident councils, community health centers, local public health service departments, independent living centers, schools, and minority educational institutions.

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- A Communication and Dissemination Plan Describe the methods and process for dissemination within the community.

- Required Personnel for R01 and R21

Although a single institution or organization must be the applicant, a multi-institutional arrangement (consortium) is possible. Such consortia, entailing active participation by more than one organization, are encouraged if there is clear evidence of close interaction and responsible partnership among the participants.

It is important to note that, because of the wide range of health problems to be addressed and the diversity of affected communities, applications must include at least one of each of the following:

- A research scientist (e.g., an epidemiological or behavioral or social scientist etc.) familiar with CBPR.
- A member of a community organization in an area having the study population. This individual must be someone who lives in or works directly and regularly with the participating community.
- In the case of intervention research, a representative of the community institutions involved in conducting the intervention activity.

Section IV. Application and Submission Information

1. Address to Request Application Information

The PHS 398 application instructions are available at <http://grants.nih.gov/grants/funding/phs398/phs398.html> in an interactive format. For further assistance contact GrantsInfo, Telephone (301) 435-0714, Email: GrantsInfo@nih.gov.

Telecommunications for the hearing impaired: TTY 301-451-0088.

2. Content and Form of Application Submission

Applications must be prepared using the PHS 398 research grant application instructions and forms. Applications must have a Dun and Bradstreet (D&B) Data Universal Numbering System (DUNS) number as the universal identifier when applying for Federal grants or cooperative agreements. The D&B number can be obtained by calling (866) 705-5711 or through the web site at <http://www.dnb.com/>. The D&B number should be entered on line 11 of the face page of the PHS 398 form.

See Section VI.2 Administrative Requirements for additional information.

The title and number of this funding opportunity must be typed on line 2 of the face page of the application form and the YES box must be checked.

3. Submission Dates

Applications are due on May 17, 2005, 2006, 2007.

3.A. Receipt, Review and Anticipated Start Dates

Application Receipt Dates: May 17, 2005, 2006, 2007

Peer Review Dates: October-November 2005, 2006, 2007

Council Review Dates: January-February 2006, 2007, 2008

Earliest Anticipated Start Dates: April 2006

3.A.1. Letter of Intent

Prospective applicants are asked to submit a letter of intent that includes the following information:

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

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 IC staff to estimate the potential review workload and plan the review.

The letter of intent is to be sent by the date listed at the beginning of this document.

The letter of intent should be sent to:

Shobha Srinivasan, Ph.D.
Chemical Exposures and Molecular Biology Branch
Division of Extramural Research and Training
National Institute of Environmental Health Sciences
P.O. Box 12233, MD EC-21
111 T.W. Alexander Drive
Research Triangle Park, NC 27709
Telephone: (919) 541-2506
FAX: (919) 316-4606
Email: sriniva2@niehs.nih.gov

3.B. Sending an Application to the NIH

Applications must be prepared using the PHS 398 research grant application instructions and forms as described above. Submit a signed, typewritten original of the application, including the checklist, and five signed photocopies in one package to:

Center for Scientific Review
National Institutes of Health
6701 Rockledge Drive, Room 1040, MSC 7710
Bethesda, MD 20892-7710 (U.S. Postal Service Express or regular mail)
Bethesda, MD 20817 (for express/courier service; non-USPS service)

3.C. Application Processing

The NIH will not accept any application in response to this PA that is essentially the same as one currently pending initial review unless the applicant withdraws the pending application. The NIH will not accept any application that is essentially the same as one already reviewed. This does not preclude the submission of a substantial revision of an application already reviewed, but such application must include an Introduction addressing the previous critique.

Although there is no immediate acknowledgement of the receipt of an application, applicants are generally notified of the review and funding assignment within eight (8) weeks.

4. Intergovernmental Review

This initiative is not subject to intergovernmental review.

5. Funding Restrictions

All awards are subject to the terms and conditions, cost principles, and other considerations described in the NIH Grants Policy Statement. The Grants Policy Statement can be found at <http://grants.nih.gov/grants/policy/policy.htm>. (See also Section VI.3. Award Criteria)

6. Other Submission Requirements

Specific Instructions for Modular Grant applications

Applications requesting up to \$250,000 per year in direct costs must be submitted in a modular budget format. The modular budget format simplifies the preparation of the budget in these applications by limiting the level of budgetary detail. Applicants request direct costs in \$25,000 modules. Section C of the research grant application instructions for the PHS 398 (rev. 5/2001) at <http://grants.nih.gov/grants/funding/phs398/phs398.html> includes step-by-step guidance for preparing modular budgets. Additional information on modular budgets is available at <http://grants.nih.gov/grants/funding/modular/modular.htm>.

Specific Instructions for Applications Requesting \$500,000 (direct costs) or More per Year.

Applicants requesting \$500,000 or more in direct costs for any year must carry out the following steps:

- 1) Contact the IC program staff at least 6 weeks before submitting the application, i.e., as you are developing plans for the study;
- 2) Obtain agreement from the IC staff that the IC will accept your application for consideration for award; and,
- 3) Include a cover letter with the application that identifies the staff member and IC who agreed to accept assignment of the application.

This policy applies to all investigator-initiated new (type 1), competing continuation (type 2), competing supplement, or any amended or revised version of these grant application types. Additional information on this policy is available in the NIH Guide for Grants and Contracts, October 19, 2001 at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-004.html>.

Plan for Sharing Research Data

Applicants requesting more than \$500,000 in direct costs in any year of the proposed research must include a **plan** for sharing research data in their application. The funding organization will be responsible for monitoring the data sharing policy. (http://grants.nih.gov/grants/policy/data_sharing).

The reviewers may assess the reasonableness of the data sharing **plan** or the rationale for not sharing research. However, reviewers will not factor the proposed data sharing **plan** into the determination of scientific merit or the priority score.

Sharing Research Resources

NIH policy requires that grant awardee recipients make unique research resources readily available for research purposes to qualified individuals within the scientific community after publication. NIH Grants Policy Statement http://grants.nih.gov/grants/policy/nihgps_2003/index.htm and http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part7.htm#_Toc54600131. Investigators responding to this funding opportunity should include a **plan** for sharing research resources addressing how unique research resources will be shared or explain why sharing is not possible.

The adequacy of the resources sharing plan and any related data sharing plans will be considered by Program staff of the funding organization when making recommendations about funding applications. The effectiveness of the resource sharing will be evaluated as part of the administrative review of each non-competing Grant Progress Report. (PHS 2590). See Section VI.3. Award Criteria.

Section V. Application Review Information

1. Criteria

Applications will be evaluated according to the standard criteria for scientific merit (Section V.3 below).

2. Review and Selection Process

Applications submitted for this funding opportunity will be assigned to the ICs on the basis of established PHS referral guidelines. Appropriate scientific review groups convened in accordance with the standard NIH peer review procedures (<http://www.csr.nih.gov/refrev.htm>) will evaluate applications for scientific and technical merit.

As part of the initial merit review, all applications will:

- Undergo a selection process in which only those applications deemed to have the highest scientific merit, generally the top half of applications under review, will be discussed and assigned a priority score
- Receive a written critique
- Receive a second level of review by the appropriate national advisory council or board.

3. Merit Review Criteria

The goals of NIH supported research are to advance our understanding of biological systems, to improve the control of disease, and to enhance health. In their written critiques, reviewers will be asked to comment on each of the following criteria in order to judge the likelihood that the proposed research will have a substantial impact on the pursuit of these goals. Each of these criteria will be addressed and considered in assigning the overall score, weighting them as appropriate for each application. Note that an application does not need to be strong in all categories to be judged likely to have major scientific impact and thus deserve a high priority score. For example, an investigator may propose to carry out important work that by its nature is not innovative but is essential to move a field forward.

1. Significance. Does this study address an important problem? If the aims of the application are achieved, how will scientific knowledge or clinical practice be advanced? What will be the effect of these studies on the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

2. Approach. Are the conceptual or clinical framework, design, methods, and analyses adequately developed, well integrated, well reasoned, and appropriate to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative tactics?

3. Innovation. Is the project original and innovative? For example: Does the project challenge existing paradigms or clinical practice; address an innovative hypothesis or critical barrier to progress in the field? Does the project develop or employ novel concepts, approaches, methodologies, tools, or technologies for this area?

4. Investigators. Are the investigators appropriately trained and well suited to carry out this work? Is the work proposed appropriate to the experience level of the principal investigator and other researchers? Does the investigative team bring complementary and integrated expertise to the project (if applicable)?

5. Environment. Does the scientific environment in which the work will be done contribute to the probability of success? Do the proposed studies benefit from unique features of the scientific environment, or subject populations, or employ useful collaborative arrangements? Is there evidence of institutional support?

3.A. Additional Review Criteria

In addition to the above criteria, the following items will be considered in the determination of scientific merit and the priority score:

Protection of Human Subjects from Research Risk: The involvement of human subjects and protections from research risk relating to their participation in the proposed research will be assessed (see the Research Plan, Section E on Human Subjects in the PHS Form 398).

Inclusion of Women, Minorities and Children in Research: The adequacy of plans to include subjects from both genders, all racial and ethnic groups (and subgroups), and children as appropriate for the scientific goals of the research will be assessed. Plans for the recruitment and retention of subjects will also be evaluated (see the Research Plan, Section E on Human Subjects in the PHS Form 398).

Care and Use of Vertebrate Animals in Research: If vertebrate animals are to be used in the project, the five items described under Section F of the PHS Form 398 research grant application instructions will be assessed.

3.B. Additional Review Considerations

Budget: The reasonableness of the proposed budget and the requested period of support in relation to the proposed research. The priority score should not be affected by the evaluation of the budget.

3.C. Sharing Research Data

Data Sharing Plan: The reasonableness of the data sharing **plan** or the rationale for not sharing research data may be assessed by the reviewers. However, reviewers will not factor the proposed data sharing **plan** into the determination of scientific merit or the priority score. The funding organization will be responsible for monitoring the data sharing policy (http://grants.nih.gov/grants/policy/data_sharing).

3.D. Sharing Research Resources

NIH policy requires that grant awardee recipients make unique research resources readily available for research purposes to qualified individuals within the scientific community after publication. NIH Grants Policy Statement http://grants.nih.gov/grants/policy/nihgps_2003/index.htm and http://ott.od.nih.gov/RTguide_final.html. Investigators responding to this funding opportunity should include a sharing research resources **plan** addressing how unique

research resources will be shared or explain why sharing is not possible.

The adequacy of the resources sharing **plan** will be considered by Program staff of the funding organization when making recommendations about funding applications. Program staff may negotiate modifications of the data and resource sharing **plans** with the Principal Investigator before recommending funding of an application. The final version of the data and resource sharing **plans** negotiated by both will become a condition of the award of the grant. The effectiveness of the resource sharing will be evaluated as part of the administrative review of each non-competing Grant Progress Report. (PHS 2590). See Section VI.3. Award Criteria.

Section VI. Award Administration Information

1. Award Notices

After the peer review of the application is completed, the Principal Investigator will also receive a written critique called a Summary Statement.

If the application is under consideration for funding, NIH will request "just-in-time" information from the applicant. For details, applicants may refer to the NIH Grants Policy Statement Part II: Terms and Conditions of NIH Grant Awards, Subpart A: General http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPS_part4.htm.

A formal notification in the form of a Notice of Grant Award (NGA) will be provided to the applicant organization. The notice of award signed by the grants management officer is the authorizing document.

Selection of an application for award is not an authorization to begin performance. Any costs incurred before receipt of the NGA are at the recipient's risk. These costs may be reimbursed only to the extent considered allowable pre-award costs.

The Notice of Grant Award will be electronically transmitted.

2. Administrative Requirements

All NIH Grant and cooperative agreement awards include the NIH Grants Policy Statement as part of the notice of grant award. For these terms of award, see the NIH Grants Policy Statement Part II: Terms and Conditions of NIH Grant Awards, Subpart A: General http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part4.htm and Part II Terms and Conditions of NIH Grant Awards, Subpart B: Terms and Conditions for Specific Types of Grants, Grantees, and Activities http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPS_part9.htm.

3. Award Criteria

The following will be considered in making funding decisions:

- Scientific merit of the proposed project as determined by peer review
- Availability of funds
- Relevance of program priorities

4. Reporting

Awardees will be required to submit the PHS Non-Competing Grant Progress Report, Form 2590 annually: <http://grants.nih.gov/grants/funding/2590/2590.htm> and financial statements as required in the NIH Grants Policy Statement.

Section VII. Agency Contacts

We encourage your inquiries concerning this funding opportunity and welcome the opportunity to answer questions from potential applicants. Inquiries may fall into three areas: scientific/research, peer review, and financial or grants management issues:

1. Scientific/Research Contacts:

Karen Bagley, M.P.H.
Program Analyst
Agency for Healthcare Research and Quality
Office of Extramural Research, Education, and Priority Populations
540 Gaither Road
Rockville, MD 20850
Telephone: 301-427-1559
Fax: 301-427-1562
E-mail: kbagley@ahrq.gov

Robert C. Freeman, Ph.D.
Division of Epidemiology and Prevention Research
National Institute on Alcohol Abuse and Alcoholism
National Institutes of Health
5635 Fishers Lane, Room 2073
Bethesda, Maryland 20892-9304
For FedEx use Rockville, MD 20852-1705
Telephone: 301-443-8820
Fax: 301-443-8614
E-mail: rfreeman@mail.nih.gov

Sabra Woolley, Ph.D.
Program, Director, Division of Cancer Control and Population Sciences
National Cancer Institute
6130 Executive Boulevard, Room 4078
Rockville, MD 20852
Telephone: 301-435-4589
Fax: 301-480-2087
E-mail: woolleys@mail.nih.gov

V. Jeffrey Evans, Ph.D.
Demographic and Behavioral Sciences Branch
National Institute of Child Health and Human Development
6100 Executive Boulevard, Room 8B07
Bethesda, Maryland 20892
Telephone: 301 496-1176
Fax: 301-496-0962
E-mail: evansvj@mail.nih.gov

Amy M. Donahue, Ph.D.
Acting Chief, Translational Research Branch
National Institute on Deafness and Other Communication Disorders
6120 Executive Blvd., EPS Room 400C
Bethesda, MD 20892-7180
Telephone: (301) 402-3458
FAX: (301) 402-6251
E-mail: donahuea@nidcd.nih.gov

Ruth Nowjack-Raymer, M.P.H., Ph.D.
Director, Health Disparities Research Program
Division of Clinical Research and Health Promotion
National Institute of Dental and Craniofacial Research
45 Center Drive, Room 4AS-43J
Bethesda, MD 20892-6401
Telephone: 301-594-5394
E-mail: nowjackr@mail.nih.gov

Jared B. Jobe, Ph.D.
Health Scientist Administrator
Behavioral Medicine and Prevention Scientific Research Group
Division of Epidemiology and Clinical Applications

National Heart, Lung, and Blood Institute
6701 Rockledge Drive, Room 8120
Bethesda, MD 20892-7936
Overnight mail zip code: 20817
Telephone: 301-435-0407
FAX: (301) 480-1773
E-mail: JobeJ@nhlbi.nih.gov

Shobha Srinivasan, Ph.D.
Chemical Exposures and Molecular Biology Branch
Division of Extramural Research and Training
National Institute of Environmental Health Sciences
P.O. Box 12233, MD EC-21
111 T.W. Alexander Drive
Research Triangle Park, NC 27709
Telephone: 919-541-2506
Fax: 919-316-4606
E-mail: sriniva2@niehs.nih.gov

David M. Stoff, Ph.D. (AIDS related applications)
Division of AIDS and Health Behavior Research
National Institute of Mental Health
National Institutes of Health
6001 Executive Blvd, Room 6210
Bethesda, MD 20892-9619
Telephone: 301-443-4625
Fax: 301-443-9719
E-mail: dstoff@mail.nih.gov

Carmen Moten-McKen, Ph.D. (non-AIDS related applications)
Division of Services and Intervention Research
National Institute of Mental Health
National Institutes of Health
6001 Executive Blvd, Room 7129
Bethesda, MD 20892-9631
Telephone: 301-443-3364
Fax: 301-443-9719
E-mail: cmoten@mail.nih.gov

Martha L. Hare, Ph.D., R.N
NIH/National Institute of Nursing Research
6701 Democracy Boulevard
One Democracy Plaza, Room 710
Bethesda, MD 20892-4870 (Courier: 20817)
Telephone: 301-451-3874
Fax: 301-480-8260
Email: Martha.hare@nih.gov

Adele M. Childress, Ph.D., M.S.P.H.
Program Administrator
Office of Extramural Programs
National Institute of Occupational Safety and Health
Centers for Disease Control and Prevention
1600 Clifton Road, N.E.
Executive Park Building 24, Room 1427, MS E-74
Atlanta, GA 30333
Telephone: (404) 498-2509
Fax: (404) 498-2571
E-mail: ahc0@cdc.gov

G. Stephane Philogene, Ph.D.
Office of Behavioral and Social Sciences Research

Office of the Director
Building 31, Room B1C32
31 Center Drive
Bethesda, MD 20892-2248
Telephone: (301) 402-3902
FAX: (301) 480-7555
E-mail: PhilogeS@od.nih.gov

2. Peer Review

Not applicable

3. Financial or Grants Management Contacts:

Marc Milton Pitts
Grants Management Specialist
Agency for Healthcare Research and Quality
OPART/GM
540 Gaither Road
Rockville, MD 20850
Telephone: (301) 427-1704
FAX: (301) 427-1462
E-mail: mpitts@ahrq.gov

William Caputo
Grants Management Specialist
National Institute on Alcohol Abuse and Alcoholism
5635 Fishers Lane, Room 3027
Bethesda, MD 20892-9304
Express Mail: Rockville, MD 20852-1705
Telephone: (301) 443-2434
FAX: (301) 443-3891
E-mail: bcaputo@mail.nih.gov

Crystal Wolfrey
Grants Administration Branch
National Cancer Institute
Executive Plaza South, Suite 243
6120 Executive Blvd
Bethesda, MD 20892
Telephone: (301) 496-8634
FAX: (301) 435-7547
E-mail: wolfreyc@mail.nih.gov

Victoria Connors
Grants Management Branch
National Institute of Child Health and Human Development
6100 Executive Boulevard, Room 8A17, MSC 7510
Bethesda, MD 20892-7510
Telephone: 301-402-6579
FAX: 301-402-0915
E-mail: connorsv@mail.nih.gov

Christopher Myers
Grants Management Officer
National Institute on Deafness and Other Communication Disorders
6120 Executive Blvd., EPS Room 400B
Bethesda, Maryland 20892-7180
Telephone: 301-402-0909
Fax: 301-402-1758
Email: myersc@mail.nih.gov

Mary Daley
Grants Management Branch
National Institute of Dental and Craniofacial Research
Building 45, Room 4AN-44B
Bethesda, MD 20892-6402
Telephone: 301-594-4808
Fax: 301-480-3562
Email: daleym@mail.nih.gov

Donald Ellis
Grants Management Specialist
NIEHS Grants Management Branch
P.O. Box 12233, MD/EC-22
Research Triangle Park, NC 27709
Telephone: 919-541-1874
FAX: 919-541-2860
Email: donaldellis@niehs.nih.gov

Rebecca Claycamp, CRA
Division of Extramural Activities
National Institute of Mental Health
6001 Executive Boulevard
Room 6122, MSC 9605
Bethesda, MD 20892-9605
Telephone: (301) 443-2811
FAX: (301) 443-6885
Email: rc253d@nih.gov

Bob Pike
Chief, Grants Management Branch
Division of Extramural Affairs
National Heart, Lung, and Blood Institute
6701 Rockledge Drive, Room 7152
Bethesda, Maryland 20892
Telephone: 301-435-0171
Fax: 301-480-0422
E-mail: piker@nhlbi.nih.gov

Teresa Marquette
Office of Grants and Contracts Management
National Institute of Nursing Research
6701 Democracy Blvd, Room 710, MSC 4870
Bethesda, MD 20892-4870
Telephone: (301) 594-2177
FAX: (301) 451-5651
Email: tm275a@nih.gov

Robin Solow
Contracts Management Branch
Centers for Disease Control and Prevention
626 Cochrans Mill Road
Pittsburgh, PA 15236-0070
Telephone: (412) 386-6428
E-mail: rsolow@cdc.gov

Section VIII. Other Information

Required Federal Citations

Use of Animals in Research:

Recipients of PHS support for activated involving live, vertebrate animals must comply with PHS Policy on Humane Care and Use of Laboratory Animals (<http://grants.nih.gov/grants/olaw/references/PHSPolicyLabAnimals.pdf>), as mandated by the Health Research Extension Act of 1985 (<http://grants.nih.gov/grants/olaw/references/hrea1985.htm>), and the USDA Animal Welfare Regulations (<http://www.nal.usda.gov/awic/legislat/usdaleg1.htm>), as applicable.

Human Subjects Protection:

Federal regulations (45CFR46) require that applications and proposals involving human subjects must be evaluated with reference to the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the research to the subjects and others, and the importance of the knowledge gained or to be gained (<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm>).

Data and Safety Monitoring Plan:

Data and safety monitoring is required for all types of clinical trials, including physiologic toxicity, and dose-finding studies (phase I); efficacy studies (Phase II) efficacy, effectiveness and comparative trials (Phase III). Monitoring should be commensurate with risk. The establishment of data and safety monitoring boards (DSMBs) is required for multi-site clinical trials involving interventions that entail potential risks to the participants (NIH Policy for Data and Safety Monitoring, NIH Guide for Grants and Contracts, June 12, 1998: <http://grants.nih.gov/grants/guide/notice-files/not98-084.html>).

Sharing Research Data:

Investigators submitting an NIH application seeking \$500,000 or more in direct costs in any single year are expected to include a plan for data sharing or state why this is not possible (http://grants.nih.gov/grants/policy/data_sharing).

Investigators should seek guidance from their institutions, on issues related to institutional policies, local IRB rules, as well as local, State and Federal laws and regulations, including the Privacy Rule. Reviewers will consider the data sharing plan but will not factor the plan into the determination of the scientific merit or the priority score.

Sharing of Model Organisms:

NIH is committed to support efforts that encourage sharing of important research resources including the sharing of model organisms for biomedical research (see <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-04-042.html>). At the same time the NIH recognizes the rights of grantees and contractors to elect and retain title to subject inventions developed with Federal funding pursuant to the Bayh Dole Act (see the NIH Grants Policy Statement http://grants.nih.gov/grants/policy/nihgps_2003/index.htm). All investigators submitting an NIH application or contract proposal beginning with the October 1, 2004 receipt date, are expected to include in the application/proposal a description of a specific plan for sharing and distributing unique model organism research resources generated using NIH funding or state why such sharing is restricted or not possible. This will permit other researchers to benefit from the resources developed with public funding. The inclusion of a model organism sharing plan is not subject to a cost threshold in any year and is expected to be included in all applications where the development of model organisms is anticipated.

Inclusion of Women And Minorities in Clinical Research:

It is the policy of the NIH that women and members of minority groups and their sub-populations must be included in all NIH-supported clinical research projects unless a clear and compelling justification is provided indicating that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. This policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43). All investigators proposing clinical research should read the "NIH Guidelines for Inclusion of Women and Minorities as Subjects in Clinical Research" (<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-001.html>); a complete copy of the updated Guidelines is available at http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm. The amended policy incorporates: the use of an NIH definition of clinical research; updated racial and ethnic categories in compliance with the new OMB standards; clarification of language governing NIH-defined Phase III clinical trials consistent with the new PHS Form 398; and updated roles and responsibilities of NIH staff and the extramural community. The policy continues to require for all NIH-defined Phase III clinical trials that: a) all applications or proposals and/or protocols must provide a description of plans to conduct analyses, as appropriate, to address differences by sex/gender and/or racial/ethnic groups, including subgroups if applicable; and b) investigators must report annual accrual and progress in conducting analyses, as appropriate, by sex/gender and/or racial/ethnic group differences.

Inclusion of Children as Participants in Clinical Research:

The NIH maintains a policy that children (i.e., individuals under the age of 21) must be included in all clinical research, conducted or supported by the NIH, unless there are scientific and ethical reasons not to include them. All investigators proposing research involving human subjects should read the "NIH Policy and Guidelines" on the inclusion of children as participants in research involving human subjects that is available at <http://grants.nih.gov/grants/funding/children/children.htm>.

Required Education on The Protection of Human Subject Participants:

NIH policy requires education on the protection of human subject participants for all investigators submitting NIH applications for research involving human subjects and individuals designated as key personnel. The policy is available at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html>.

Human Embryonic Stem Cells (hESC):

Criteria for federal funding of research on hESCs can be found at <http://stemcells.nih.gov/index.asp> and at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-005.html>. Only research using hESC lines that are registered in the NIH Human Embryonic Stem Cell Registry will be eligible for Federal funding (see <http://escr.nih.gov/>) It is the responsibility of the applicant to provide in the project description and elsewhere in the application as appropriate, the official NIH identifier(s) for the hESC line(s) to be used in the proposed research. Applications that do not provide this information will be returned without review.

Public Access to Research Data through the Freedom of Information Act:

The Office of Management and Budget (OMB) Circular A-110 has been revised to provide public access to research data through the Freedom of Information Act (FOIA) under some circumstances. Data that are (1) first produced in a project that is supported in whole or in part with Federal funds and (2) cited publicly and officially by a Federal agency in support of an action that has the force and effect of law (i.e., a regulation) may be accessed through FOIA. It is important for applicants to understand the basic scope of this amendment. NIH has provided guidance at http://grants.nih.gov/grants/policy/a110/a110_guidance_dec1999.htm. Applicants may wish to place data collected under this PA in a public archive, which can provide protections for the data and manage the distribution for an indefinite period of time. If so, the application should include a description of the archiving plan in the study design and include information about this in the budget justification section of the application. In addition, applicants should think about how to structure informed consent statements and other human subjects procedures given the potential for wider use of data collected under this award.

Standards for Privacy of Individually Identifiable Health Information:

The Department of Health and Human Services (DHHS) issued final modification to the "Standards for Privacy of Individually Identifiable Health Information", the "Privacy Rule", on August 14, 2002. The Privacy Rule is a federal regulation under the Health Insurance Portability and Accountability Act (HIPAA) of 1996 that governs the protection of individually identifiable health information, and is administered and enforced by the DHHS Office for Civil Rights (OCR).

Decisions about applicability and implementation of the Privacy Rule reside with the researcher and his/her institution. The OCR web site (<http://www.hhs.gov/ocr/>) provides information on the Privacy Rule, including a complete Regulation Text and a set of decision tools on "Am I a covered entity?" Information on the impact of the HIPAA Privacy Rule on NIH processes involving the review, funding, and progress monitoring of grants, cooperative agreements, and research contracts can be found at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-025.html>.

URLs in NIH Grant Applications or Appendices:

All applications and proposals for NIH funding must be self-contained within specified page limitations. Unless otherwise specified in an NIH solicitation, Internet addresses (URLs) should not be used to provide information necessary to the review because reviewers are under no obligation to view the Internet sites. Furthermore, we caution reviewers that their anonymity may be compromised when they directly access an Internet site.

Healthy People 2010:

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2010," a PHS-led national activity for setting priority areas. This PA is related to one or more of the priority areas. Potential applicants may obtain a copy of "Healthy People 2010" at <http://www.health.gov/healthypeople>.

Authority and Regulations:

This program is described in the Catalog of Federal Domestic Assistance at <http://www.cfda.gov/> and is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review. Awards are made under the authorization of Sections 301 and 405 of the Public Health Service Act as amended (42 USC 241 and 284) and under Federal Regulations 42 CFR 52 and 45 CFR Parts 74 and 92. All awards are subject to the terms and conditions, cost principles, and other considerations described in the NIH Grants Policy Statement. The NIH Grants Policy Statement can be found at <http://grants.nih.gov/grants/policy/policy.htm>.

The PHS strongly encourages all grant recipients to provide a smoke-free workplace and discourage the use of all tobacco products. In addition, Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of a facility) in which regular or routine education, library, day care, health care, or early childhood development services are provided to children. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

1. Centers for Disease Control and Prevention. (2003). Secondary Conditions: Children and Adults with Disabilities. Available at: http://www.cdc.gov/ncbddd/factsheets/secondary_cond.pdf. Accessed April 29, 2003.

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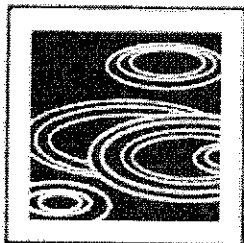
Department of Health
and Human Services



National Institutes of Health (NIH)
9000 Rockville Pike
Bethesda, Maryland 20892

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Nonprofit Innovation Award

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Let us know if you would like to be informed when our 10 finalists are selected.

Amazon.com is proud to announce that it is now accepting applications for the Amazon.com Nonprofit Innovation Award, which recognizes and rewards nonprofit organizations whose innovative approaches most effectively improve their communities or the world at large. If your nonprofit is powered by breakthrough ideas, we encourage you to read more about our program and how to apply for the award.

Ten organizations selected as finalists will have a unique opportunity to raise funds and awareness for their programs on Amazon.com. All 10 finalists will be profiled on their own Amazon.com pages, where customers will be invited to vote for their favorites by making monetary donations. The organization that receives the largest amount of customer contributions by the deadline will receive the award, along with a matching grant of up to \$1 million from Amazon.com.

Eligibility Requirements

To be eligible to enter, the organization must be recognized by the U.S. Internal Revenue Service (IRS) as exempt from federal income tax under IRC §501(c)(3), qualify as a charitable organization under IRC §170(b)(1)(A)(vi) and have public charity status under IRC §509. The organization also must have been in existence for a minimum of two years and may not have Amazon.com employees, officers, or directors serving as employees, officers, or directors.

The Amazon.com Nonprofit Innovation Award is specifically **not** targeting:

- New or start-up business plans
- Programs promoting religious doctrine or ideologies
- Organizations that discriminate on a basis of race, creed, gender, or sexual orientation in policy or in practice

Award Criteria

The selection of semifinalists and finalists from the pool of eligible entrants will be based on criteria that include:

- **Need:** the urgency, relevancy and complexity of the problem the organization seeks to address.
- **Gap analysis:** clear evidence of a gap between the targeted problem and existing solutions.
- **Innovation:** the extraordinary inventiveness of the solution and how it breaks from traditional approaches.
- **Results:** clearly defined metrics and a measurable record of improvement for at least two years.
- **Perpetuation:** a well-developed plan for promoting continued innovation.



Selection Process

The process for selecting the winner of the Amazon.com Nonprofit Innovation Award has three phases:

1. Stanford Business School's Center for Social Innovation, in conjunction with Amazon.com, will review applications against established criteria and select a set of semifinalist organizations by May 2005.
2. A panel will join Amazon to narrow the list to the 10 most effective and compelling programs in June 2005. Panelists scheduled to participate include Muhammad Ali, sports legend and humanitarian; Dr. Henry Kissinger, former United States Secretary of State; Téa Leoni, actress and National Ambassador to U.S. Fund for UNICEF; Dr. Lawrence M. Bernabo, one of Amazon.com's leading customer reviewers; Jeff Bradach, managing partner and co-founder of leading U.S. nonprofit consulting firm The Bridgespan Group; James A. Phillips, Jr., co-director of the Stanford Center for Social Innovation; and Jeff Bezos, CEO and founder of Amazon.com.
3. Amazon.com customers will vote with their pocketbooks. Beginning July 19, 2005, the 10 nonprofit finalist organizations will be profiled on the Amazon.com site, where customers and visitors will be able to find, discover, and make direct online contributions to their favorites. Donations will be accepted through September 30. The organization that receives the largest total contributions from Amazon customers will be granted the 2005 Amazon.com Nonprofit Innovation Award, along with a matching grant of up to \$1 million from Amazon.com. The 2005 honoree will be announced in October 2005.

Timeline

4/28/05	Deadline for Amazon.com to receive completed applications
7/19/05	Finalists announced; online donations begin
9/30/05	Deadline for customer donations
10/12/05	Winner announced

How to Apply

It's simple. First, download the application form. If you have any questions, please refer to the Award FAQ, which contains additional information. Then send us your completed form, along with the additional required documents by April 28, 2005. You will receive a confirmation e-mail within three business days of our receiving your materials. Amazon.com will follow up with you if we need any additional information.

If your organization does not qualify for the program but is still interested in other opportunities available through Amazon.com, please see [OUR Resources for Nonprofits page](#).

About Stanford Business School's Center for Social Innovation

The Stanford Graduate School of Business developed the Center for Social Innovation to foster innovative solutions to social problems by enhancing the leadership, management, and organization capacity of individuals and institutions pursuing the creation of social and environmental value. The Center dissolves traditional sector boundaries by bringing together nonprofit leaders, corporate executives, government officials, and philanthropists to discuss, debate, analyze, and take action to strengthen communities. The center's core activities--research, teaching, and community engagement--focus on many thematic areas, including corporate social responsibility, social entrepreneurship, environmental sustainability, philanthropy, education, and nonprofit management. To learn more, visit Stanford's Center for Social Innovation Web site.

Instant Order Update for Dr Leslie Korn:

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- Your January 16 order is being processed -- more details.

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