

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Native American Research Centers for Health (NARCH) Grants

Announcement Type: New and Competing Continuations.

Funding Announcement Number: HHS-2010-IHS-NARCHVI-0001.

Catalog of Federal Domestic Assistance Numbers (s): 93.933.

Key Dates: Letter of Intent Deadline: March 15, 2009.

Application Deadline Date: May 14, 2009.

Review Date: October, 2009.

Earliest Anticipated Start Date: June 1, 2010.

I. Funding Opportunity Description

The Indian Health Service (IHS), in conjunction with the National Institute of General Medical Sciences (NIGMS) and other institutes of the National Institutes of Health (NIH) announces competitive grant applications for Native American Research Centers for Health (NARCH), an initiative to support new and/or continuing centers or projects funded under the NARCH grant program. This funding mechanism will develop further opportunities for conducting research and research training to meet the needs of American Indian/Alaska Native (AI/AN) communities. This program is authorized under the Snyder Act, 25 U.S.C. 13, the Public Health Service Act, 42 U.S.C. 241 as amended, and the Indian Health Care Improvement Act, 25 U.S.C. 1602(a)(b)(16). This program is described at 93.933 in the Catalog of Federal Domestic Assistance.

Background Information:

The AI/AN Tribal nations and communities have long experienced health status worse than that of other Americans. Although major gains in reducing health disparities were made during the last half of the twentieth century, most gains stopped by the mid-1980s (Trends in Indian Health 1998–99) and a few diseases, e.g., diabetes, worsened. "All Indian" rates contain marked variation among the IHS Areas or regions (Regional Differences in Indian Health 1998–99); and variation by Tribe exists within Areas as well. The Trends and Regional Differences reference can be found at the IHS Web site at: http://www.ihs.gov/NonMedicalPrograms/IHS_Stats. Although the AI/AN mortality rates for all cancers are about 20 percent lower than the U.S. rates for all races, there is variation among IHS Areas for specific

cancers. Moreover, the favorable AI/AN mortality rates for some cancers may be due to markedly lower incidence rates partly offset by higher case-fatality rates. Unfamiliarity with modern health care may adversely influence health status among the elderly, the low-income elderly, and Tribes, and also may reduce the acceptability of health research among them. The daunting tasks confronting Tribes, researchers, and health care and public health programs in the beginning of the twenty-first century are to resume the reduction of health disparities that had occurred through the 1980s, to reverse the worsening in a few diseases, to maintain and strengthen the favorable status, and to reduce the disparities among and within Areas and Tribes. Factors known to contribute to health status and disparities are complex, and include underlying biology, physiology, and genetics, as well as ethnicity, culture, socioeconomic status, gender/sex, age, geographical access to care, and levels of insurance.

Additional factors known to contribute to health status and disparities include:

1. Family, home, and work environments;
2. General or culturally specific health practices;
3. Social support systems;
4. Lack of access to culturally appropriate health care; and
5. Attitudes toward health.

Yet none of these alone, or in combination, accounts for all documented differences. Health disparities of AI/ANs may also reflect a lack of in-depth research relevant to improving their health status. Many AI/ANs distrust research for historical reasons. One approach that combats this distrust is to ensure that Tribes are the managing partners in training and research that involves them, as for example, in community-based participatory research (i.e., a collaborative research process between researchers and community representatives). This approach is especially helpful to design both training relevant to researchers from Tribal communities, and research relevant to the health needs of the communities.

Research Objectives:

The NARCH initiative will support partnerships between Federally recognized AI/AN Tribes or Tribal organizations (including national and area Indian health boards, and Tribal colleges meeting the definition of a Tribal organization as defined by 25 U.S.C. 1603(d) or (e)) and institutions

that conduct intensive academic-level biomedical, behavioral and health services research. These partnerships are called Native American Research Centers for Health (NARCH). Due to the complexity of factors contributing to the health and disease of AI/ANs, and to their health disparities compared with other Americans, the collaborative efforts of the agencies of the Department of Health and Human Services (HHS) and the collaboration of researchers and AI/AN communities are needed to achieve significant improvements in the health status of AI/AN people. To accomplish this goal, in addition to objectives set by the Tribe, Tribal organization or Indian health boards, the IHS NARCH program will pursue the following program objectives:

- To develop a cadre of AI/AN scientists and health professionals—Opportunities are needed to develop more AI/AN scientists and health professionals engaged in research, and to conduct biomedical, clinical, behavioral and health services research that is responsive to the needs of the AI/AN community and the goals of this initiative. Faculty/researchers and students at each proposed NARCH will develop investigator-initiated, scientifically meritorious research projects, including pilot research projects, and will be supported through science education projects designed to increase the numbers of, and to improve the research skills of, AI/AN investigators and investigators involved with AI/ANs.

- To enhance partnerships and reduce distrust of research by AI/AN communities—Recent community-based participatory research suggests that AI/AN communities can work collaboratively in partnership with health researchers to further the research needs of AI/ANs. Fully utilizing all cultural and scientific knowledge, strengths, and competencies, such partnerships can lead to better understanding of the biological, genetic, behavioral, psychological, cultural, social, and economic factors either promoting or hindering improved health status of AI/ANs, and generate the development and evaluation of interventions to improve their health status. Community distrust of research and researchers will be reduced by offering the Tribe greater control over the research process.

- To reduce health disparities—In the Indian Health Care Improvement Act, Public Law 94–437 (as amended), IHS was legislatively mandated to improve the delivery of effective health care to AI/ANs. In the NIH Revitalization Act of 1993, NIH was encouraged to increase

the number of under-represented minorities participating in biomedical, clinical, and behavioral research, including studies on drug abuse and alcoholism, and the examination of the role of resiliency in the prevention and treatment of those conditions. Also, the "Initiative to Eliminate Racial and Ethnic Disparities in Health" by HHS (<http://www.omhrc.gov/rah>) encouraged NIH to help reduce health disparities. In response to these priorities, the IHS and NIH have established a collaboration to support the NARCH.

Reducing health disparities among AI/AN communities and individuals may be fostered by greater understanding of how to enhance their strengths and resilience. While AI/AN communities have relied on health research and medical science to reduce health disparities, they have also relied on their own psychological, organizational, and cultural assets and strengths to survive major harms and disruptions over the centuries, and to rebound from insults to health.

The mission of NIH is to acquire new knowledge that will lead to better health by understanding the processes underlying health and disease that in turn will help prevent, detect, diagnose, and treat disease and disability. The NARCH initiative works toward the NIH mission by supporting research that discovers the interrelationships among the many factors that contribute to health and disease, and by helping to train and promote AI/AN researchers and researchers concerned with AI/AN health.

II. Award Information

Type of Awards: Grant.

Estimated Funds Available: The estimated funds (total costs) available for the first year of support for the entire initiative is expected to be at least \$2.0 million in Fiscal Year 2010. The actual amount may vary, depending on the response to the request for applications (RFA) and availability of funds. An applicant may request a project period not to exceed four years of support, and direct costs not to exceed \$1,100,000 per center or \$550,000 per project (research or training) in the first year of each award. Direct costs to the applicant include the total cost of each subcontract (subcontractor direct plus subcontractor indirect costs).

Anticipated Number of Awards: An estimated five to fifteen awards will be made under the program.

Award Amount: \$100,000–\$1,100,000 per year.

III. Eligibility Information

The new or existing NARCH must be a working partnership of the eligible AI/AN organization and of the research-intensive institution. Applicants eligible to receive the NARCH award are Federally recognized Tribes and Tribal organizations as defined under the Indian Health Care Improvement Act, 25 U.S.C. 1603 (d) or (e), including eligible Indian health boards or Tribal colleges applying on behalf of eligible Federally recognized Tribes or Tribal organizations. As the grantee, the eligible AI/AN organization will define criteria and eligibility for participation in all aspects of the partnership, consistent with this announcement. A minimum of 30 percent of the grant funds must be budgeted in the application to remain with the eligible AI/AN organization(s); that is, no more than 70 percent of the application's total budget may be contained in subcontract budgets of the non-eligible subcontracting partner institutions or organizations.

1. Eligible Applicants—The AI/AN applicant must be one of the following:

- A federally recognized AI/AN Tribe, as defined under 25 U.S.C. 1603(d); or
- A Tribal organization, as defined under 25 U.S.C. 1603(e), including Tribal colleges or health boards meeting this definition; or
- A consortium of two or more of those Tribes or Tribal organizations. Applicants other than Tribes must provide proof of non-profit status.

2. Cost Sharing or Matching—The NARCH program does not require matching funds or cost sharing.

3. The Research-Intensive Partner—The Research-Intensive Partner must be an accredited public or private nonprofit university, academic medical center, or other institution that has an established record of conducting research into the health problems of AI/AN; has demonstrated a commitment to enhancing the capability of AI/AN faculty/researchers, students, investigators, and communities to engage in biomedical, behavioral, clinical and health services research; and has demonstrated a commitment to mentoring AI/AN faculty/researchers, students, and investigators.

4. Principal Investigator—The Principal Investigator, the individual responsible for the administration (including fiscal management) of the overall project, must have his/her primary appointment with the AI/AN applicant organization. Special arrangements of employment, such as inter-organizational personnel

agreements, are permissible. The Principal Investigator may be, but is not required to be, the NARCH Program Director or a Research Project Investigator. The NARCH Principal Investigator may or may not have formal academic/research credentials, but if not, then the NARCH Program Director must be so qualified.

The traditional NIH research project grant consists of a single Principal Investigator (PI) working with a small group of subordinates on an independent research project. Although this model clearly continues to work well and encourages creativity and productivity, it does not always work well for multidisciplinary efforts and collaboration. Increasingly, health-related research involves teams that vary in terms of size, hierarchy, location of participants, goals, disciplines, and structure. There is growing consensus that team science would be encouraged if more than one PI could be recognized on individual awards. The NIH has adopted a multiple-PI model, as recently directed by the Office of Science and Technology Policy. All agencies that have research and research-related programs must offer the multiple-PI model as an option. Note, it is only an option, not a requirement. The traditional NARCH division of roles between PI and Project Director will usually address these issues to a satisfactory degree. For additional information regarding the new multiple-PI model, please click on the following website: http://grants.nih.gov/grants/multi_pi/index.htm.

5. NARCH Program Director—The NARCH Program Director is the individual responsible for the day-to-day leadership and management of the research and training programs within the proposed NARCH. The Program Director may be, but is not required to be, the Student and Faculty/Researcher Development Director or a Research Project Investigator. The NARCH Program Director may or may not have formal academic/research credentials, but if not, then the Principal Investigator must be so qualified.

6. Student and Faculty/Researcher Development Director and Participant—The NARCH initiative is an institutional developmental grant mechanism that places an emphasis on the continual development of students and faculty/researchers. If a new Student and/or Faculty/Researcher Development Program is proposed in the current application, then the Principal Investigator of that project is expected to be the NARCH Student and Faculty Development Director. In order to be included as the Student and Faculty

Development Director, the prospective director must have a faculty/researcher appointment at the research-intensive institution (or equivalent appointment at the AI/AN organization or other consortium partner) and must demonstrate that he/she has the knowledge, skills, and capabilities to mentor students and faculty/researchers and to generate and direct development and mentoring programs.

The Student and Faculty Development Director may be the NARCH Program Director. Faculty/researchers and students should be supported in research education activities that improve their skills and abilities to be successful at the next stage of their professional development. To be included as a participant for faculty/researcher development in the proposed NARCH, the individual must have a faculty/researcher appointment at the research-intensive institution or equivalent appointment at the AI/AN organization or consortium partner.

7. Research Project Investigators—The NARCH initiative is an institutional developmental grant mechanism that places an emphasis on continual improvement of the research competitiveness of the research investigators. In order to be included as a research project investigator in the NARCH, a prospective investigator must have a faculty appointment at the research-intensive institution or equivalent appointment at the AI/AN organization or other consortium partner, and must show that he/she has the need, based on institutional, departmental, and professional development plans, to enhance his/her research knowledge, skills, and capabilities by engaging in the proposed research program and associated activities.

8. Tribal Approval of the Application—It is the policy of the IHS that all research involving AI/AN Tribes be approved by the Tribal governments with jurisdiction. Therefore, the following documentation is required as part of the application for new or continuing centers or additional NARCH projects:

- Tribal Resolution:

If the applicant is an Indian Tribe or Tribal organization, a resolution supporting the project from the Tribal government of all Tribes to be served must accompany the application submission. Applications by Tribal organizations will not require resolutions if the current Tribal resolutions under which they operate would encompass the proposed activities. In this instance, a copy of the current resolution must accompany the

application. The listed Tribes to be served by the project in the proposal must match the set of appended resolutions. If a resolution from an appropriate representative of each Tribe to be served is not submitted prior to October 1, 2009, the application will be considered incomplete and will not be considered for funding.

An official signed resolution must be received by October 1, 2009 by the Division of Grants Operations (DGO), IHS, at the Reyes Building, 801 Thompson Avenue, TMP 360, Rockville, MD 20852. A grant will not be awarded unless the signed resolution is received. Please include the funding opportunity number, as a reference to this announcement, if the resolutions are submitted as a separate mailing.

9. Mechanism of Support—Awards under this initiative will be administered using the competing institutional grant mechanism of the IHS, and will be reviewed using the NIH S06 mechanism.

IV. Application and Submission Information

1. Address to Request Application Package: NARCH Program Official, Reyes Building, 801 Thompson Avenue, Rockville, MD 20852 or by e-mail to narch@ihs.gov. Applicants are strongly encouraged to establish eligibility of their proposed applications prior to submission. Inquiries about eligibility should be addressed to Alan Trachtenberg, M.D., M.P.H., at (301) 443-0578 or by e-mail to narch@ihs.gov. The application package, including supplemental instructions will be posted on the IHS Research Program Web site, at: <http://www.ihs.gov/MedicalPrograms/Research/narch.cfm>. Technical assistance will be made available for applicants, and first time applicants are urged to take advantage of it. To sign up for technical assistance, potential applicants should e-mail their contact information to narch@ihs.gov with the words “technical assistance” in the subject heading and full contact information, including email address, listed in the body of the e-mail.

The NIH instructions for the PHS 398 application form are available in an interactive format at: <http://grants.nih.gov/grants/funding/phs398/phs398.html>. Applicants must use the currently approved version of the PHS 398. For further assistance contact GrantsInfo, Telephone (301) 435-0714, e-mail: GrantsInfo@nih.gov, Telecommunications for the hearing impaired: TTY 301-451-0088.

Submit a typed and signed original application, including the Checklist, and one (1) single-sided photocopy of

the entire application (including Appendices and supporting documents) in one package to: Division of Grants Operations, Indian Health Service, Reyes Building, 801 Thompson Avenue, TMP 360, Rockville, MD 20852-1627 (zip code is unchanged for express/courier services), Telephone: (301) 443-5204.

“Native American Research Centers for Health” and the RFA number NOT-GM-09-010 must be typed on line 2 of the face page of the application form and the YES box must be marked.

At the time of submission, applicants must also send four (4) additional single-sided photocopied and signed applications, including the Checklist, Appendices, and supporting documentation to: Center for Scientific Review (CSR), National Institutes of Health, 6701 Rockledge Drive, Room 6160—MSC 7892, Bethesda, MD 20892-7720, Bethesda, MD 20817 (for express or courier service). Telephone: (301) 435-0715. The CSR no longer accepts hand delivered applications. E-mail or other electronic applications will not be accepted under this announcement.

Specific supplementary instructions for the PHS 398 application and budget preparation for the NARCH program may be obtained from the initiative contacts listed under VII. Agency Contacts, and will be posted at: <http://www.ihs.gov/MedicalPrograms/Research/narch.cfm>. They will also be sent to any potential applicant who e-mailed their contact information to narch@ihs.gov with the words “technical assistance” in the subject heading.

There will be no acknowledgment of receipt of the application.

2. Content and Form of Application Submission:

A proposed NARCH may include any or all of the following components: Student development projects; faculty/researcher development projects; research projects (including pilot projects); and “core” administrative facilities.

The content of the application should explain the components of the application, and how they help meet the purposes of the NARCH initiative. A description should be provided of the current state of the research and research training enterprise at the proposed NARCH and its institutional and community partners, including faculty/researcher and student profiles.

A clear statement should be presented of the overall goals, specific measurable objectives, and anticipated milestones. These elements should be presented in the context of needed improvements in the partners’ organizational

infrastructure and environment for research. Documentation should be provided to establish that the research-intensive partner is an institution with a record of conducting research into the health of AI/ANs, and that it has a demonstrated commitment to the special encouragement of, and assistance to, AI/AN faculty/researchers, students, investigators, and communities for enhancing their capacity to engage in biomedical, behavioral and health services research. For competitive renewals of existing NARCH grants, previous accomplishments and progress from the time of the initial NARCH award must be described. Documentation about the nature of the partnership itself should be included, such as: the process to develop the application and proposed NARCH itself, the past and future efforts to increase the capacity of the partners to improve their partnership, and efforts to contribute to the success of the NARCH. Applicants are encouraged to articulate plans for the development of partnerships toward the possible planning of a national native health research conference or other national research training. The development of additional future collaborative research and research training opportunities should also be an integral part of each NARCH core proposal. For previously existing NARCH centers, a specific and detailed list of accomplishments and assessment of the benefits from the previous NARCH grant(s) is required.

A plan for assessment of the benefits of the activities by the proposed NARCH on specific, measurable outcomes identified in the application should be provided. IHS and NIGMS recognize that Tribes, Tribally-based organizations, and research-intensive institutions are diverse in their missions, their health and economic status, and their cultures. Such an assessment for a new NARCH could include a self-study by the proposed NARCH and its partners, which focuses on fact-finding, program evaluation, and recommendations for improvement in key areas.

Strategies for determining the initial and ongoing success of their efforts for organizational development should also be presented. It is expected that each proposed NARCH will develop its own set of strategies that best match its circumstances. Guidance and suggestions for program evaluation of a proposed NARCH can be obtained from <http://www.the-aps.org/education/promote/promote.html>. For applications that are competing renewals of existing NARCH centers, the report and evaluation of the progress made under

the previous NARCH grant(s) will be a key part of the application.

Applicants are strongly urged to contact NARCH initiative staff at an early stage to request the specific supplementary instructions for the PHS 398 for the NARCH grants. Supplementary instructions may be obtained from the initiative contacts listed under VII. Agency Contacts, and will be posted at: <http://www.ihs.gov/MedicalPrograms/Research/narch.cfm>. They will also be sent to any potential applicant who e-mailed their contact information to narch@ihs.gov with the words "technical assistance" in the subject heading.

If Student Development Projects are proposed, the NARCH application should describe new programs or modifications or additions to existing programs of the partners that encourage and facilitate AI/AN students to enter, advance, and remain in health research careers. Such projects might include, but are not limited to, providing employment as research assistants in research projects of research-active mentors with an explicit mentoring plan, providing other mentoring with an explicit mentoring plan, providing workshops to improve technical or communication skills, providing motivating seminars or journal clubs highlighting problems of interest to students, providing contact with role models, and providing opportunities to travel to present results at national scientific meetings. If research mentorships or apprenticeships are proposed, the application should clearly document the experience, proposed commitment, and quality of the mentors in providing guidance and advice to students (including responsible conduct of research and research integrity, teaching, and protection of human subjects), and in fostering the development of academic and/or community-based AI/AN researchers.

The application should describe how the development plans for the students will meet both the individuals' professional development goals, and one purpose of the NARCH initiative: To develop a cadre of AI/AN scientists and health professionals. The application must have an evaluation plan for the new project(s) that indicates the anticipated outcomes relative to the current baseline data. For example, one outcome might be the improved retention of AI/AN students in science majors. The application should indicate the anticipated (quantitative) improvement relative to the current retention rate. Accomplishments of (and connections with) any previously funded NARCH student development

projects by the applicant or partners must be described.

A student in a NARCH Student Development Project must be a full-time or part-time student officially enrolled in an educational program leading to an undergraduate or graduate degree, or in a post-doctoral educational program, or (if well justified) in late high school. A helpful book about mentoring science students is found at <http://books.nap.edu/catalog/5789.html>.

If Faculty/Researcher Development Projects are proposed, the NARCH application should describe the need, proposed activity, and anticipated outcomes. Faculty/researcher development projects might include, but are not limited to, short-term mentored research experiences in the lab of an active NIH-extramurally-funded researcher with an explicit mentoring plan, long-term general mentoring under an explicit mentoring plan, or attendance at workshops or courses or national meetings needed for acquiring specific skills or methodologies needed for prospective research. As with student development projects, the application should document the experience, proposed commitment, and quality of the mentors, teachers, or experience in providing guidance and advice to faculty/researchers, and in fostering the development of academic and community-based AI/AN research. The application must also describe the evaluation plan for the faculty/researcher development project. The application must clearly describe how the development plans for faculty/researchers will meet both the individuals' professional development goals, and two purposes of the NARCH initiative:

- To develop a cadre of AI/AN scientists and health professionals, and
- To enhance the partnership of the proposed NARCH.

For grantees with previous NARCH funding for faculty/researcher development projects, a detailed list of the accomplishments of (and connections with) any previously funded NARCH faculty/researcher development projects by the applicant or partners must be described.

NARCH applications may include a maximum of five (5) regular Research Projects and a maximum of five (5) Pilot Research Projects. Unlike regular research projects, a pilot research project is limited in scope and is not expected to have preliminary data. It is also limited to a budget of no more than \$75,000 direct costs per year for four years. The pilot research project is intended for faculty/researchers without current Federal research support.

Support for faculty/researchers participating in pilot research projects is preparatory to seeking more substantial funding from NIH research grant programs (e.g., Academic Research Enhancement Award, K, and R01 awards), as well as funding from other agencies and private sources. Funds received from the proposed NARCH to support pilot research projects may not be used to supplement ongoing research projects. A NARCH application need not include both research projects and pilot research projects. Applications for only pilot research projects or for only research projects may be submitted. Individual project investigators may propose either a research project or a pilot research project, but not both. For research projects that are continuations or modifications or outgrowths of research projects (including pilot research projects) under previous NARCH grants, the accomplishments of the previous research project(s) should be detailed and a logical description given as to how the results of the previous work has led to the current proposal.

Each research project or pilot research project should follow the instructions provided in PHS 398 (Revised 11/2007) for preparing research grant applications. The professional development goals must clearly describe specific objectives and milestones which should include, but are not limited to, improving competitiveness in acquiring grant support. The applicant should describe how successful completion of the proposed research project will improve the research skills and will help develop the students and faculty/researchers, thus contributing to the overall goals and specific measurable objectives of the proposed NARCH.

Each research project or pilot research project must follow the IHS policy concerning Tribal approval, that all research involving AI/AN Tribes be approved by the Tribal governments with jurisdiction. That is, each grantee must include a resolution of approval from the Tribal government(s), or (if applicable) a letter of support signed by the Executive Director or CEO of the eligible AI/AN organization, or both (if applicable) for projects that involve people or community(ies) of an AI/AN Tribe, or an eligible Tribal organization. For NARCH proposals from multi-Tribal consortia with projects that involve only one or a few of the Tribes of the consortium, some description should be provided as to the process through which the particular Tribes were chosen to participate.

Research projects (including pilot research projects) proposed under this initiative must be in research areas normally funded by any of the NIH or other research agencies in the HHS. Research projects addressing health disparities and the health priorities of the AI/AN partner are especially encouraged.

A listing of grants recently funded by NIH may be found at Computer Retrieval of Information on Scientific Projects (CRISP), a searchable database of Federally-funded biomedical research projects conducted at universities, hospitals, and other research institutions. It may be accessed at <http://report.nih.gov/crisp/crispquery.aspx>. The following agencies, institutes, offices, and centers have stated particular interests in supporting research under the NARCH Program as follows:

National Institute of Dental and Craniofacial Research (NIDCR)

Oral Health Research

NIDCR is committed to reducing the disproportionate burden of oral diseases experienced by AI/ANs. The focus of NIDCR's health disparities research is on improving oral health status and quality of life by understanding and addressing oral diseases that are prevalent in AI/AN communities, specifically caries (including early childhood caries), oral and pharyngeal cancer, and periodontal disease. Interdisciplinary research teams and the full participation of communities are viewed by NIDCR as essential components of any health disparities research.

Data that document oral disease prevalence are readily available for some populations, but not for others. Homogeneity in subgroups of populations cannot be assumed. For instance, there are national data for Mexican Americans, but not for the numerous other Hispanic subgroups. Similarly, data regarding the oral health status of various AI/AN Tribes are unavailable. Moreover, available data provide little insight into the etiology or determinants of oral disease and oral health. The paucity of quality data and conceptual models concerning the broad array of potential determinants and risk-factors inhibits progress toward preventing disease, and improving oral health status and quality of life. The NIDCR invites applications that, in preparation for intervention research, explore the complex array of social, behavioral, psychological, contextual, environmental, and biological factors and their interactions that may

contribute to oral health disparities within AI/AN communities. Including oral health status measures within broader epidemiologic studies is encouraged. However, applications that are limited to the assessment of disease prevalence and that explore a very limited range of potential determinants will be considered non-responsive.

The NIDCR has particular interest in intervention research that will provide clinically meaningful outcomes and essential information needed to inform clinical practice, public health policy, health care provision, community and/or individual action. Intervention studies that are grounded in theory are needed. Both basic and applied intervention research applications are invited. Studies may need to intervene at multiple levels within communities. The NIDCR encourages the use of the strongest research design possible and recognizes that not all intervention research is amenable to randomized clinical trials. Examples of health disparities intervention research of interest to the NIDCR includes but are not limited to:

- Effectiveness studies that tailor/target preventive approaches to communities/individuals;
- Research that intervenes in novel ways on macro- or intermediate level determinants of oral health status;
- Health services research that explores alternative approaches to delivering preventive oral health care;
- Studies that intervene on common risk factors or that take a systems approach;
- Studies that explore multifaceted strategies to intervene at several levels within society;
- Dissemination and implementation research at multiple organizational levels; and
- Research that uses appropriate technology for translation, implementation, adoption, adherence, and acceptance of oral disease prevention programs in defined populations, clinics, and communities.

Intervention research should be reasonably applicable to a specific AI/AN population. To facilitate adequate enrollment and generalizability, intervention studies may need to be conducted at multiple sites. Studies may be conducted at a single site only if enrollment is adequate and if sufficient numbers of participants are available to allow extrapolation of clinically meaningful results to the specific AI/AN population of interest. Pilot research projects that are designed to lead to larger research projects funded as part of a center or as

free-standing NIH grants may be proposed.

For additional information about oral health research contact: Ruth Nowjack-Raymer, M.P.H., PhD, Director, Health Disparities Research Program, National Institute of Dental and Craniofacial Research, 6701 Democracy Blvd., Room 640, Bethesda, MD 20892-4878, Phone: (301) 594-5394, Fax: (301) 480-8322, e-mail: nowjackr@mail.nih.gov.

National Institute on Drug Abuse (NIDA)

Neuroscience and Drug Abuse Research:

AI/ANs demonstrate higher rates of drug abuse, particularly methamphetamine, tobacco and alcohol abuse, relative to other racial subgroups. According to 2002-2006 National Survey on Drug Use and Health (NSDUH) data, AI/AN past year methamphetamine use was 1.4% compared to 0.1% for African Americans, 0.6% for Hispanics or Latinos and 0.7% for Whites. Prevalence of use is high in both men and women.

Drug abuse patterns among AI/AN are complex and can vary by factors such as Tribe and geographic location. While some datasets are available that can provide general epidemiological data regarding use and abuse rates in this group, data are needed that better clarify where use rates are highest, among which Tribes, age and gender groups and the factors that predict drug abuse in these locales and groups. These data will assist in developing more targeted interventions and in identifying mechanisms related to drug abuse which can then serve as focal points for intervention.

In addition to scarce data on patterns of use, limited data are available assessing drug abuse prevention and treatment interventions for AI/AN. The matrix model has been proposed in particular to address methamphetamine abuse, but few data are available to assess the efficacy of this approach with this population. Several preventive interventions have been designed particularly for this population and results from them indicate their value, but more research is needed to clarify why these sometimes don't work in expected ways and whether the interventions that are being used but have not been evaluated are working to reduce drug use.

The NIDA is committed to reducing health disparities in drug abuse and related health and social consequences among AI/AN. Further, the Institute supports methodologies required by the NARCH, expecting that studies be

developed and implemented using community participatory approaches.

Research topics of interest include but are not limited to:

- Studies that explore a range of behavioral, cultural, environmental, and individual factors that contribute to drug abuse;
- Studies that explore the consequences of drug abuse among AI/ANs;
- Studies that consider the full context of drug abuse, including poverty, family factors, school factors, intergenerational trauma, etc.;
- Studies that explore the role of traditional practices and spirituality in protecting against drug abuse;
- Studies that explore other factors that protect against use in those groups for whom use rates are lower;
- Studies that explore the efficacy and/or effectiveness of culturally relevant preventive interventions;
- Studies that explore the efficacy and/or effectiveness of culturally relevant treatment interventions;
- Studies that assess factors related to service utilization, including use rates and access to services, either in reservation or urban settings; and
- Studies that explore the organization, management and delivery of interventions.

For additional information about neuroscience or drug abuse research contact: Kathy Etz, PhD, National Institute on Drug Abuse, 6001 Executive Blvd., Room 5153 MSC 9589, Bethesda, MD 20852, Phone: (301) 402-1749, Fax: (301) 480-2543, e-mail: Kathleen.Etz@nih.hhs.gov.

National Institute on Alcohol Abuse and Alcoholism (NIAAA)

Alcohol Research

NIAAA is committed to reducing the disproportionately high burden of illness associated with alcohol use, abuse, and dependence among AI/AN people. Alcohol-associated disability-adjusted life years (DALYs) remain highest among AI/ANs in comparison to all other U.S. ethnic groups. AI/AN people suffer from unacceptably high rates of alcohol abuse and dependence, alcohol-related morbidity and mortality, and intentional and unintentional injuries associated with alcohol use. Nevertheless, AI/AN people are heterogeneous on many dimensions with over 562 Federally-recognized Tribal entities. To address alcohol-related health disparities of AI/AN people, more needs to be known about how differences between Tribes, geographic regions, residence on reservations, urban or rural areas, as

well as more typical demographic variables such as age, education, income, and gender influence alcohol use and associated health status outcomes. Such information can guide the development of more effective and culturally appropriate ways of identifying and intervening with those who suffer from alcohol-related problems, as well as preventing alcohol problems before they occur. Additional research is also needed to understand how to best advance the dissemination of research findings on alcohol and health, so that AI/AN people can benefit from the latest research discoveries. Finally, NIAAA is aware that oftentimes researchers who conduct investigations among communities of color are members of these cultural, racial or ethnic groups themselves. NIAAA is committed to identifying and providing training and mentoring experiences to help AI/AN alcohol researchers advance the science of alcohol use and give back to their communities.

The NIAAA is committed to reducing alcohol related health disparities and is committed to the NARCH program. Research topics of interest to NIAAA include but are not limited to:

- Studies that assess the differing needs of various Tribal groups, considering variations in rates of alcohol use, misuse and abstinence.
- Studies that develop new interventions or adapt existing prevention and/or treatment interventions that take strengths of the AI/AN culture into consideration.
- Studies that investigate the application/adaptation of evidence based interventions among AI/AN groups.
- Studies that investigate how traditional spiritual and medical treatments can be applied/adapted to improve intervention outcomes among AI/AN peoples.
- Studies that explore the effectiveness and/or efficacy of commonly used interventions such as screening and brief intervention or referral among AI/AN populations.
- Studies that investigate the risk and protective factors associated with drinking among women of childbearing age so as to inform culturally sensitive, effective FASD prevention.
- Studies that investigate ways to delay onset of youth drinking among AI/AN young people.
- Studies that investigate the association between alcohol use and suicide among AI/AN people, especially youth. Studies may attempt to understand the individual and

group level variables that contribute to “epidemics” of suicide among AI/AN youth.

- Studies that explore the consequences of alcohol use and misuse among AI/AN peoples; these consequences may include but are not limited to other social and health problems (*i.e.*, diabetes, obesity, poor nutrition, cancer, liver disease, etc.), interfamilial violence, intentional and unintentional injury, and driving under the influence.
- Studies that investigate the acceptance and efficacy of pharmacotherapy for alcohol abuse and dependence within integrated health counseling approaches.
- Studies that investigate the influence of alcohol use on the spread and treatment of Human Immunodeficiency Virus (HIV)/Acquired Immune Deficiency Syndrome (AIDS) among AI/AN peoples.

For additional information contact:

Judith A. Arroyo, PhD, Minority Health and Health Disparities Coordinator, Project Official, Division of Epidemiology and Prevention Research, National Institute on Alcohol Abuse and Alcoholism, 5635 Fishers Lane Room 2079, Bethesda, MD 20892–9304, (for Fed Ex use Rockville, MD 20852–1705), Office: 301–402–0717, Fax: 301–443–8614, e-mail: Judith.Arroyo@nih.hhs.gov.

National Cancer Institute (NCI)

Cancer Health Disparities Research

The Center to Reduce Cancer Health Disparities (CRCHD) is committed to reducing cancer health disparities among AI/ANs. Investigators are encouraged to submit research projects addressing every aspect of cancer and cancer health disparities research. CRCHD welcomes investigations in basic, clinical, translational, and population-based research addressing cancer health disparities among AI/AN. The CRCHD is central to the NCI's efforts to reduce the unequal burden of cancer in our society. As part of these efforts, the Diversity Training Branch, CRCHD, has been supporting NARCH projects with cancer relevance since 2003.

For additional information contact:

Dr. Peter Ogunbiyi, Program Director, Diversity Training Branch, Center to Reduce Cancer Health Disparities, National Cancer Institute, 6116 Executive Boulevard, Suite 602, Bethesda, MD 20892–8341 (U.S. Postal Service), Phone: 301–496–7344, Fax: 301–435–9225, e-mail: po43t@nih.gov.

Health Literacy Research:

The HHS, in its Healthy People 2010 initiative, defines health literacy as, “the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions.” (Please see: <http://www.healthypeople.gov/document/HTML/Volume1/11HealthCom.htm>). Health literacy is a complex phenomenon that involves individuals, families, communities, and systems. For instance, consumers, patients, caregivers, traditional healers, or other laypersons may vary with respect to:

- Access (e.g., to audience-appropriate information, media or professionals);
- Skills (e.g., to gather and comprehend health information; to speak and share personal information about health history and symptoms; to act on information by initiating appropriate follow-up visits and conveying understanding back to the information source; to make decisions about basic healthy behaviors, such as healthy eating and exercise; to engage in self-care and chronic disease management);
- Knowledge (e.g., of health and medical vocabulary, concepts such as “risk”, the organization and functioning of healthcare systems, cultural beliefs and possible differences in traditional and current medical systems about disease causation, prevention and treatment);
- Abilities (e.g., sensory, communication, cognitive, or physical challenges or limitations);
- Features of health care providers and public health systems (e.g., the communication skills of health professionals, platforms employed for patient education, built environments, and signage);
- Traditional healers and their role, especially in relation to the existing medical systems which could lead to different understanding in health and disease progression;
- Demographics (e.g., developmental or life stage, cultural, linguistic, or educational differences that affect health beliefs, knowledge, and communication).

Too often people with the greatest health burdens have limited access to relevant health information. One reason is the complex and cumbersome ways in which health information is presented. Health care professionals may not communicate effectively with individuals. For instance, achieving informed consent for treatment is

difficult when health care personnel cannot explain biological processes or treatment procedures in simplified language and patients cannot interpret health information. These situations hamper the effectiveness of health professionals' efforts to prevent, diagnose, and treat medical conditions, and limit many health care consumers' abilities to make important health care decisions. Another reason is due to individuals' limited abilities to fully interpret and understand complex health terminology and instructions. This could be further exacerbated by different belief systems and adoption of methods for prevention and treatment. Limited numeracy can also impede the ability to make personal decisions related to risk, risk avoidance, and risk reduction. For instance, to follow health care instructions, patients need to be able to comprehend written and oral prescription instructions, directions for self-care, and plans for follow-up tests and appointments.

Specific Objectives

Researchers are strongly encouraged to review the general illustrative examples of topics relevant to health literacy provided below. Applications should address health promotion, prevention, treatment, or management of diseases or health conditions, and/or the improvement of health or health care outcomes. The research must involve at least one of the following:

- Health literacy, or one of its many components, as a key outcome;
- Health literacy as a key explanatory variable for some other outcome;
- Methodological or technological improvement to strengthen research on health literacy; and/or
- Prevention and/or intervention strategies that focus on health-literacy.

Studies to develop, or evaluate, the readability or utility of specific materials that are intended for single uses or single audiences are not responsive to this program announcement unless these investigations are integral to testing a significant research hypothesis related to health literacy.

Approaches

A wide variety of research approaches are encouraged:

- Basic research that investigates or describes the nature of health literacy and the magnitude of health literacy problems;
- Applied research addressing issues pertinent to health literacy practices (e.g., systems level interventions) and research-in-practice (e.g., active

potential end users participate as supportive research partners);

- Develop theoretical models, refine research constructs, improve methods and measurements, and establish causal relationships (e.g., between low health literacy and lack of effective health promotion);

- Evaluation research that develops and tests the effectiveness of interventions, or adapts and tests existing programs (including those that are implemented by health care systems and systems outside of health care), to reduce low health literacy and its adverse consequences;

- Secondary analyses of existing datasets as well as meta-analytic studies; and

- Multilevel, multidisciplinary, interdisciplinary, and transdisciplinary research is encouraged, especially studies that incorporate individual, family, community and societal mediators of health literacy in childhood and adulthood, or state-of-the-art health communication theory and knowledge.

For additional information about NCI health literacy research contact: Sabra F. Woolley, Ph.D., Program Director, Health Communication and Informatics Research Branch, National Cancer Institute, 6130 Executive Blvd. Room 4084, Bethesda, Maryland 20892-7365, Phone: 301-435-4589, Fax: 301-480-2087, E-mail: Sabra.Woolley@nih.hhs.gov.

Tobacco Control Research

AI/ANs have been documented to have the highest smoking rate of any major racial/ethnic group in the U.S. According to the 2005 National Health Interview Survey of adults 18 and over, 32% of AI/AN are current smokers, compared with 21.9% of non-Hispanic whites, 21.5% of non-Hispanic blacks, 13.3% of Asians and 16.2% of Hispanics. Prevalence of smoking is high among both men (37.5%) and women (26.8%).⁽¹⁾ A similar pattern can be seen among youth, where AI/AN youth have substantially higher smoking prevalence (23.1%) than non-Hispanic whites (14.9%), Hispanics (9.3%), non-Hispanic blacks (6.5%), and Asians (4.3%), according to data from the National Survey on Drug Use and Health. These data also show that non-smoking AI/AN youth demonstrated higher susceptibility to experimenting with smoking than most other racial/ethnic groups.⁽²⁾

At the same time, however, tobacco use patterns among the AI/AN population are complex and can vary substantially among subgroups of this population. Smoking rates among AI/

ANs vary widely by region, being highest in the northwestern United States, in Canada, and in Alaska. Additionally, use of smokeless tobacco is higher among AI/AN adults compared with other racial/ethnic groups. Some studies have found particularly high rates of smokeless tobacco use (greater than 50%) among AN populations, including pregnant women, due to the use of Iqmik, a traditional form of smokeless tobacco.⁽³⁾

Understanding tobacco use among Native American populations is also complicated by the fact that tobacco has had a substantial role in Native American culture and tradition. Historically, tobacco has been used in medicinal and healing rituals and in ceremonial and religious practices. It is important to distinguish the traditional, ceremonial uses of tobacco, which are limited to specific occasions, from addictive use of tobacco products. However, the relationship between these different contexts of tobacco use and their impact on behavior has not received sufficient scientific study.

Moreover, limited data are available on the effectiveness of tobacco use cessation interventions targeted to AI/ANs. Preliminary focus group studies suggest that Native American smokers are more likely to have negative attitudes towards pharmacotherapies, such as concerns about side effects and lack of trust in conventional medicine.⁽⁴⁾ Thus, there is a need to develop culturally-appropriate interventions targeted to this population.

The NCI Tobacco Control Research Branch is committed to supporting transdisciplinary research aimed at reducing disparities in tobacco use and related health outcomes. The NARCH provides a unique mechanism to support collaborative research involving researchers from multiple disciplines to address a complex scientific and public health challenge.

Sample research areas of interest include but are not limited to the following:

- Studies to understand the role of a range of behavioral, cultural, and environmental factors that lead to initiation of tobacco use among AI/AN populations;
- Development and evaluation of culturally appropriate interventions for tobacco use prevention and cessation targeted to AI/AN populations;
- Studies of how tobacco related attitudes and behaviors in youth and adults are influenced by ceremonial tobacco use and other cultural factors;
- Studies of tobacco use behavior in relation to different products, including

dual use of cigarettes and smokeless tobacco;

- Research on the characteristics, use, and health effects of traditional tobacco products, such as Iqmik;
- Research to understand disparities in tobacco use within AI/AN populations given substantial variations by region and other factors; and
- Studies to identify and address barriers to treatment among AI/ANs.

References

1. Tobacco Use Among Adults—United States, 2005. MMWR. October 27, 2006; 55: 1145–1148.
2. Racial/Ethnic Differences Among Youths in Cigarette Smoking and Susceptibility to Start Smoking—United States, 2002–2004. MMWR. December 1, 2006; 55: 1275–1277.
3. Renner CC, Patten CA, Day GE, Enoch CC, Schroeder DR, Offord KP, Hurt RD, Gasheen A, Gill L. Tobacco use during pregnancy among Alaska Natives in western Alaska. *Alaska Med.* 2005;47:12–16.
4. Burgess D, Fu SS, Joseph AM, Hatsukami DK, Solomon J, van Ryn M. Beliefs and experiences regarding smoking cessation among American Indians. *Nicotine Tob Res.* 2007;9 Suppl 1:S19–28.

For additional information about NCI tobacco research contact: Mark Parascandola, PhD, Epidemiologist, Tobacco Control Research Branch, National Cancer Institute, 6130 Executive Blvd. MSC 7337, Executive Plaza North, Room 4039, Bethesda, MD 20892, Phone: 301-451-4587, Fax: 301-496-8675, E-mail: paramark@mail.nih.gov.

National Heart, Lung, and Blood Institute (NHLBI)

Cardiovascular and Respiratory Research

The NHLBI has a strong history of supporting research to document and intervene on health disparities among AI/ANs, including the Strong Heart Study, Pathways, Genetics of Coronary Artery Disease in Alaska Natives (GOCADAN), the Stop Atherosclerosis in Native Diabetics Study (SANDS), and Community-Responsive Interventions to Reduce Cardiovascular Risk in AI/ANs.

The Strong Heart Study showed that many AI/AN communities bear a heavy burden of cardiovascular disease (CVD) and cardiovascular risk factors (e.g., obesity, diabetes) that could be reduced through effective interventions on modifiable risk factors. The high burden of disease will worsen unless behaviors and lifestyles affecting CVD risk can be changed. Prevalence of obesity in AI/AN communities is about 50% higher than in the U.S. general population, in which obesity is often described as being of epidemic proportions. In some AI/AN communities, cigarette smoking,

sedentary lifestyle, and stress augment the adverse effects of obesity. AI/ANs are particularly vulnerable to Type 2 diabetes, a problem exacerbated by high rates of obesity. Diabetes prevalence is 3–20 fold higher among AI/ANs than in the general U.S. population. It is an important cause of coronary heart disease, cardiomyopathy, end-stage renal disease, non-traumatic amputation, and vision impairment. Lipid abnormalities also are common in Type 2 diabetics, particularly high triglycerides and low HDL-cholesterol levels. Dyslipidemia and blood pressure can be improved by appropriate changes in diet and by increased exercise. CVD risk is also substantially improved by smoking cessation. In addition, attention to high stress levels, untreated sleep disordered breathing, short sleep duration, and depression may be warranted, because of evidence that they may influence the health behaviors of interest. For example, poorer diet, higher smoking rates, and physical inactivity are more prominent in those with high stress, sleep disorders, or depression. These psychosocial factors also are associated with CVD progression in observational epidemiologic studies, and there is evidence from smaller clinical studies that they may affect mechanisms leading to CVD. NHLBI is interested in supporting research in AI/AN communities that promotes the adoption of healthy lifestyles and/or improves behaviors related to cardiovascular risk, such as weight reduction, regular physical activity, and smoking cessation. These behaviors and lifestyles are known to affect biological cardiovascular risk factors, such as hypertension, dyslipidemia, obesity, glucose intolerance, and diabetes. In addition, control of these risk factors by guideline-based use of antihypertensive, lipid lowering, and hypoglycemic drugs can reduce their adverse consequences. However, these pharmacological interventions are often suboptimally utilized in AI/AN communities. The NHLBI is interested in reducing cardiovascular disease mortality and morbidity in AI/AN, whether by lifestyle changes, drug interventions, or combinations thereof.

Lifestyles characterized by sleeping less than 7 hours per night are associated with increased risk of CVD, obesity, diabetes, and all-cause mortality. Insufficient sleep and poor sleep quality is associated with abnormalities in hypothalamic-pituitary axis function and behavioral stress. Sleep deprivation compromises vigilance, judgment, mood, emotional

expression, and other aspects of cognition increasing the risk of unstable patterns of behavior. The ability of sleep deprivation to enhance the encoding and recall of emotional (relative to neutral) memories may profoundly influence social interactions and stress. Insufficient sleep is associated with an increased risk of new onset substance abuse and relapse, and new onset depression and relapse. Intervention studies to assess the efficacy of improving sleep as part of a healthy lifestyle or assessing how improving sleep disorders could improve CVD outcomes would be of interest to NHLBI. Sleep disordered breathing appears to be 30–60% more common among American Indians than other racial and ethnic groups. Sudden infant death syndrome occurs 2.5 times more frequently in AI/AN children than in white children, and 2.0 times more frequently than in the U.S. population as a whole.

AI/AN also have been documented to exhibit high rates of chronic respiratory disease. AI/AN adults have the highest asthma rate among single-race groups. Recent evidence suggests that 11.6 percent of AI/AN suffer from asthma. This is significantly higher than the national average of 7.5 percent, and much higher than every other single racial or ethnic group. Chronic obstructive pulmonary disease (COPD), which includes emphysema and chronic bronchitis, is the sixth leading cause of death from chronic disease for AI/AN men and the seventh leading cause of death for women. AI/AN have the second highest rates of cystic fibrosis following whites. One in 10,500 AI/AN has cystic fibrosis compared with one in 3,200 whites. Pueblo Indians and Zuni Indians have higher incidence than among other AI/AN Tribes. NHLBI is interested in supporting research in AI/AN communities that includes studies of approaches to improve clinical delivery of efficacious treatments of chronic lung disease and their risk factors, improved methods of chronic lung disease self-management, studies to promote or maintain respiratory health or improved methods of rehabilitation for diseases of the lungs and airways, such as asthma, COPD, cystic fibrosis; sleep disordered breathing, occupational lung diseases, pulmonary vascular disease or pulmonary complications of AIDS.

In addition to these areas of research, the NHLBI recognizes a unique and compelling need to promote diversity in the biomedical, behavioral, clinical, and social sciences research workforce. The NHLBI expects efforts to diversify the workforce to lead to:

- The recruitment of the most talented researchers from all groups;
- An improvement in the quality of the educational and training environment;
- A more balanced perspective in the determination of research priorities;
- An improved capacity to recruit subjects from diverse backgrounds into clinical research protocols; and
- An improved capacity to address and eliminate health disparities.

For more information, please contact: Jared B. Jobe, Ph.D. (Cherokee), Program Director, Clinical Applications and Prevention Branch, Division of Prevention and Population Sciences, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Suite 10018, MSC 7936, Bethesda, Maryland 20892–7936 (20817 express), Phone: (301) 435–0407, Fax: (301) 480–5158, E-mail: JobeJ@mail.nih.gov.

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

Research in Osteoporosis and other Bone Diseases, Osteoarthritis, Rheumatoid Arthritis and Skin Disease Within the NIAMS Mission

The NIAMS supports efforts to conduct 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 research progress to improve the public health. Goals specific to the AI/AN communities involve research addressing the training of underrepresented minority AI/AN researchers and ensuring inclusion of Native communities in clinical research studies. NIAMS actively monitors the inclusion of minority populations in clinical research and will highlight any grants that specifically target AI/AN populations. The mission of the NIAMS 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. Studies in these mission areas as they relate to the AI/AN population may be proposed.

For additional information about research in these areas contact: Dr. Phil Tonkins, National Institute of Arthritis and Musculoskeletal and Skin Diseases, 6701 Democracy Blvd., Suite 800, Bethesda, MD 20912, Phone: (301) 594–4979, Fax: (301) 480–1284, E-mail: tonkinsw2@mail.nih.gov.

National Center for Complementary and Alternative Medicine (NCCAM)

Research on Traditional Healing Practices

Many AI/AN communities use traditional healing practices to prevent and/or treat diseases and to maintain health. NCCAM is interested in supporting research on traditional healing practices with these goals in mind. NCCAM is also interested in research on the safe and effective integration of conventional care with traditional healing practices for AI/AN communities. The methodological feasibility for integration has yet to be addressed for many traditional healing practices. Consequently, NCCAM is interested in supporting developmental studies to identify and address difficult methodological and design issues particular to traditional healing practices, as well as to allow for the development of contextually and culturally sensitive research mirroring the values of AI/AN communities.

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

- Qualitative research to characterize and document healing practices and diagnostic approaches of indigenous peoples, and study the feasibility of research on those practices and approaches in future clinical studies;
- Observational studies to explore patient and care provider preferences, beliefs, attitudes, and patient-provider interactions;
- Case-control, observational, and other studies to understand traditional healing strategies from multiple perspectives, including: (a) Optimal dosing, duration, and frequency of treatment; (b) type of treatment; (c) examinations of different healing practices to treat a particular disease/condition; (d) comparisons of complex versus simple interventions; (e) evaluation of adherence among patient populations to interventions with varying levels of complexity; and (f) examination of potentially important individual differences that mediate or moderate treatment outcome;
- Studies to determine if traditional healing practices can be translated into a broader clinical setting, in terms of: Reliability, responsiveness and utility; assessment procedures, instruments, and tools in psychosocial, functional, and physiological domains;
- Studies to construct and validate culturally sensitive data collection instruments; to design and pilot outcome measures consistent with the tenets of traditional, indigenous systems of medicine and comparisons of these

outcome measures to those commonly used by conventional biomedicine; and

- Health services research of established AI/AN traditional healing practices to explore the factors that influence access to and use of such therapies; the nature, cost effectiveness, and quality of such care; and ultimately the effects on health and well-being.

For additional information on NCCAM-supported research topics, contact:

Sheila A. Caldwell, Ph.D., Program Officer, Office of Special Populations, National Center for Complementary and Alternative Medicine, 6707 Democracy Boulevard, Suite 401, MSC 5475, Bethesda MD, 20892-5475, Phone: (301) 594-3396, Fax: (301) 480-3621, E-mail: caldwells@mail.nih.gov.

Office of Research on Women's Health (ORWH)

Women's Health Research

The ORWH at the NIH supports research related to women's health and the study of sex and gender differences. Detailed information about the NIH Research Priorities for Women's Health, can be found at <http://orwh.od.nih.gov/research.html>.

For additional information on women's health research, contact: Lisa Begg, Dr. P.H., R.N., Director of Research Programs, NIH Office of Research on Women's Health, 6707 Democracy Blvd., Suite 400, Bethesda, MD 20892-5484, Phone: (301) 496-7853, Fax: (301) 402-1798, E-mail: begg1@od.nih.gov.

National Institute of Mental Health (NIMH)

Research projects aimed at understanding the burden, treatment, intervention or prevention of mental disorders and Human Immunodeficiency Virus (HIV)/AIDS in AI/AN populations

Indigenous people in the United States are disproportionately affected by mental illness and HIV infection, as are the larger racial and ethnic populations such as African Americans and Latinos. AI/ANs are highly underrepresented in the physician workforce, as researchers, and in health research in general, numbering fewer than one hundred. Other factors that contribute to disparities that affect these communities include geographic isolation, poor access to health services, underutilization of health services, insufficient screening and partner management services, social and cultural norms, linguistics, stigma, and gender. Research is needed to identify and address the impact as well as the

specific and unique aspects of mental disorders and HIV infection upon Native American communities. A critical component of response to mental health and HIV infection in Native American communities will be to identify, train, mentor, and develop Native American investigators. Towards these ends, a promising model is community-based participatory research together with community capacity building.

Areas of interest to the NIMH that can contribute to scientific knowledge about mental health and HIV interventions in Native Americans include, but are not limited to research studies:

- To investigate the clinical epidemiology of mental disorders and HIV infection across all clinical and service settings (e.g., primary care);
- To investigate research methods/community assessment to eliminate mental health disparities;
- To evaluate the impact of traumatic stress and other social, cultural, interpersonal, and environmental factors on risk for and course of mental disorders;
- To examine patient, provider, and contextual factors that influence diagnosis, help-seeking decisions and preferences, and the helping relationship;
- To understand processes underlying HIV and mental illness stigmas and discrimination in Native American communities;
- To develop and assess effective strategies and approaches for reducing HIV and mental illness stigmas and discrimination;
- To evaluate the effectiveness of treatment, pharmacologic, psychosocial (psychotherapeutic and behavioral), somatic, rehabilitative, and combination interventions on mental and behavior disorders—including acute and longer-term therapeutic effects on functioning for children, adolescents, and adults;
- To develop and tailor/target interventions to communities/individuals of Native Americans;
- To employ interventions that improve quality and outcomes of care (including diagnostic, treatment, preventive, and rehabilitation services);
- To conduct scientifically rigorous investigations of culturally appropriate interventions, prevention, and control strategies;
- To employ services interventions that remove barriers to care leading to the elimination of mental health disparities;
- To conduct studies of 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, schools);

- To enhance research infrastructure and build research capacity for conducting intervention and services research;
- To explore alternative approaches (e.g., telehealth) to translating, delivering, implementing, and disseminating mental health care;
- To investigate adaptation, evaluation, safety, and costs of proven interventions;
- To explore dissemination and implementation strategies at multiple organizational levels; and
- To examine the role of community stakeholders in the research process, especially readiness for change.

For additional information on NIMH NonAIDS Applications contact: Carmen P. Moten, Ph.D., Chief, Primary Care, Socio Cultural and Disparities Research Programs, Division of Services and Intervention Research, National Institute of Mental Health, 6001 Executive Boulevard, Room 7131, MSC 9631, Bethesda, MD 20892-9631, Phone: (301) 443-3725, Fax: (301) 443-4045, E-mail: cmoten@mail.nih.gov.

For additional information on NIMH HIV/AIDS-related applications contact: David M. Stoff, Ph.D., Chief, HIV/AIDS Neuropsychiatry Program, AIDS Research Training and HIV/AIDS Disparities Program, Division of AIDS and Health and Behavior Research, National Institute of Mental Health, 6001 Executive Boulevard, Room 6210, MSC 9619, Bethesda, MD 20892-9619, Phone: (301) 443-4625, Fax: (301) 443-9719, E-mail: dstoff@mail.nih.gov.

For additional information on NIMH research on Stigma and Health Disparities contact: Emeline Otey, Ph.D., Chief, Stigma and Health Disparities Program, Division of AIDS and Health and Behavior Research, National Institute of Mental Health, 6001 Executive Boulevard, Room 6227, MSC 9615, Bethesda, MD 20892-9615, Phone: (301) 443-9284, Fax: (301) 480-2920, E-mail: eotey@mail.nih.gov.

National Institute of Biomedical Imaging and Bioengineering (NIBIB) Research in Technology for Health

The National Institute of Biomedical Imaging and Bioengineering (NIBIB) is committed to reducing health disparities through the development of new and affordable biomedical technologies. To this end, the NIBIB is interested in supporting the translation of biomedical technologies that target

the health needs of AI/AN communities. Specifically, the NIBIB is interested in supporting the development of technologies that have broad therapeutic and interventional applications as well as technologies that complement technology development in all program areas of the NIBIB, <http://www.nibib.nih.gov/Research/ProgramAreas>.

For additional information about NIBIB programs contact: John W. Haller, Ph.D., National Institute of Biomedical Imaging and Bioengineering, NIH/DHHS, 6707 Democracy Blvd., Suite 200, Bethesda, MD 20892-5649, Phone: (301) 451-4780, Fax: (301) 480-1614, E-mail: John.Haller@nih.hhs.gov.

National Eye Institute (NEI)

Vision Research

The NEI supports research and health information dissemination with the goal of protecting and prolonging the vision of the American people. Examples of such activity that may be of interest include, but are not limited to:

- Epidemiological studies to determine the prevalence and possible risk factors of eye diseases and disorders among AI/AN populations;
- Basic research studies into the causes and mechanisms of eye diseases and visual impairments in AI/AN, research into disparities in access to ophthalmic/optometric health services; and,
- Development and evaluation of culturally appropriate health education and intervention.

For additional information on vision research topics contact: Jerome R. Wujek, Ph.D., National Eye Institute, 2020 Vision Place, Bethesda, MD 20892-3655, Phone: (301) 451-2020, Fax: (301) 402-0528, E-mail: wujekjer@nei.nih.gov.

THE OMISSION ABOVE OF ANY NIH INSTITUTE, CENTER, OFFICE, OR RESEARCH AREA SHOULD NOT BE TAKEN AS A LACK OF AVAILABILITY OF SUPPORT FOR PROJECTS IN THOSE AREAS. NARCH is an NIH-wide partnership, led at NIH by the National Institute of General Medical Sciences (NIGMS). General research priorities for all of the individual NIH Institutes, Centers, Divisions and Offices can be found on their respective Web sites at: <http://www.nih.gov/icd/index.html>. However, applicants and potential academic partners are reminded that *the NARCH program is focused on the research needs of the tribes and not those of the federal or academic partners.*

Previous NARCH grants have been funded by the following partners:

- National Institute of General Medical Sciences (NIGMS);
- National Cancer Institute (NCI);
- National Heart, Lung, and Blood Institute (NHLBI);
- National Human Genome Research Institute (NHGR);
- National Institute on Alcohol Abuse and Alcoholism (NIAAA);
- National Institute of Allergy and Infectious Diseases (NIAID);
- National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS);
- National Institute of Dental and Craniofacial Research (NIDCR);
- National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK);
- National Institute on Drug Abuse (NIDA);
- National Center for Complementary and Alternative Medicine (NCCAM);
- National Center on Minority Health and Health Disparities (NCMHD);
- NIH Office of Behavioral and Social Sciences Research (OBSSR);
- NIH Office of Research on Women's Health (ORWH); and
- Agency for Healthcare Research and Quality (AHRQ).

In addition to these partners within HHS, the Federal Collaborative on Health Disparities Research (FCHDR), Headquartered in the HHS Office of Minority Health (OMH) is in the process of seeking co-funding partnerships for the NARCH program with other departments and agencies of the Federal Government. Any additional information that develops after the publication of this announcement will be posted on the NARCH program Web site at <http://www.ihs.gov/MedicalPrograms/Research/narch.cfm> and disseminated to the TECHASSISTANCE-NARCH listserve developed from persons e-mailing their contact information to narch@ihs.gov.

Public Policy Requirements: All Federal-wide public policies apply to IHS grants with exception of the Lobbying and Discrimination public policy.

3. Submission Dates and Times

A. Letter of Intent Deadline: March 15, 2009

Prospective applicants are asked to submit a letter of intent that includes the title of the new project(s) proposed, the name, address, and telephone number of the project Principal Investigator(s), the identities of the partners and of key personnel, and the number and title of this RFA. The letter of intent should be received before 5 p.m. Eastern Standard Time on March 15, 2009, by Mushtaq A. Khan, D.V.M.,

Ph.D., Chief, Digestive and Respiratory Sciences IRGs, Center for Scientific Review, MSC 7818, Room 2176; 6701 Rockledge Drive; Bethesda, MD 20892 (20817 for express or courier service). Phone: (301) 435-1778; Fax (301) 451-2043; E-Mail: khanm@csr.nih.gov.

Letters may be submitted by mail, fax or e-mail. 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 the IHS and NIH Center for Scientific Review (CSR) staffs to estimate the potential review workload and avoid conflict of interest in the review.

B. Application Deadline: May 14, 2009

The applications must be received before 5 p.m. Eastern Standard Time on May 14, 2009, at the Center for Scientific Review (CSR) National Institutes of Health, 6701 Rockledge Drive, Room 6160—MSC 7892, Bethesda, MD 20892-7720, Bethesda, MD 20817 (for express or courier service). Phone: (301) 435-0715 and at the IHS Division of Grants Operations (DGO) Indian Health Service, Reyes Building, 801 Thompson Avenue, TMP Suite 360, Rockville, MD 20852-1627 [zip code is unchanged for express/courier services], Phone: (301) 443-5204. Applications received after this date will be returned to the applicant. Competing applications not meeting the deadline date specified in the announcement are considered late applications and will not be considered for funding under this announcement. The CSR will not accept any application in response to this RFA that is essentially the same as one currently pending initial review, unless the applicant withdraws the pending application.

The CSR will not accept any application that is essentially the same as one already reviewed. This does not preclude the submission of substantial revisions of applications already reviewed, but such applications must include an introductory letter addressing the previous critique.

4. Intergovernmental Review

This funding opportunity is not subject to Executive Order 12372, "Intergovernmental Review of Federal Programs." A State approval is not required.

5. Funding Restrictions

- Pre-award costs are allowable pending prior approval from the awarding agency. However, in accordance with 45 CFR part 74 all pre-award costs are incurred at the

recipient's risk. The awarding office is under no obligation to reimburse such costs if for any reason the applicant does not receive an award or if the award to the recipient is less than anticipated.

- The available funds are inclusive of direct and appropriate indirect costs.
- Only one grant/cooperative agreement will be awarded per applicant under this announcement.
- IHS will not acknowledge receipt of applications.

- Grantees are allowed a reasonable period of time in which to submit required financial and performance reports. Failure to submit required reports within the time allowed may result in suspension or termination of an active grant, withholding of additional awards for the project, or other enforcement actions such as withholding of payments or converting to the reimbursement method of payment. Continued failure to submit required reports may result in the imposition of special award provisions, or cause other eligible projects or activities involving that grantee organization, or the individual responsible for the delinquency to not be funded. Failure to obtain prior approval for change in Scope, Principal Investigator, Grantee Institutions, Successor in Interest, or Recipient Institute Name, undertaking any activities disapproved or restricted as a condition of the award, may result in fund restrictions.

6. Other Submission Requirements

Each submitted research project (including pilot research projects) must be budgeted so that it could stand on its own. That is, each project should be fundable under its own budget so that it could be completed even if none of the rest of the NARCH is funded. All things vital to each project should be included in the budget of that project and not included in the core. The NARCH core should include only administrative, training or other items that are non-essential to the research projects. The core should also include the capacity to take advantage, for training purposes, of any new research opportunity that becomes available to the grantee, whether through NARCH funding or other new resources. The core should be budgeted as if it were an additional project and the total amounts requested on the face page of the NARCH application should represent the sum of the projects plus the core. Each subcontractor participating in each project (or core) should submit its budget as part of that project's budget, using appropriate form pages from the

PHS 398. Each project submission should include a set of budget pages from each of the institutional partners participating in that project. Each research project budget should explicitly include that portion of the grantee's indirect costs that are associated with activities under that project, including direction and oversight of the subcontracts. Each project (and core) must include a checklist and face page for that project. Only the main face page for the entire NARCH is required to have the signatures of the NARCH principal investigator and official signing for the applicant organization.

Submit a typed and signed original application, including the checklist, and one single-sided photocopy of the entire application (including Appendices and supporting documents) in one package to: Division of Grants Operations, Indian Health Service, Reyes Building, 801 Thompson Avenue, TMP Suite 360, Rockville, MD 20852-1627 (zip code is unchanged for express/courier services), Phone: (301) 443-5204.

At the time of submission, applicants must also send four additional single-sided photocopied and signed applications, including the Checklist, Appendices, and supporting documentation to: Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6160--MSC 7892, Bethesda, MD 20892-7720, Bethesda, MD 20817 (for express or courier service). Phone: (301) 435-0715. The CSR no longer accepts hand delivered applications. E-mail or other electronic applications will not be accepted under this announcement.

Specific supplementary instructions for the PHS 398 application and budget preparation for the NARCH program may be obtained from the initiative contacts listed under VII. Agency Contacts, and will be posted at <http://www.ihs.gov/MedicalPrograms/Research/narch.cfm>. They will also be sent to any potential applicant who e-mailed their contact information to narch@ihs.gov with the words "technical assistance" in the subject heading.

DUNS Number

Applicants are required to have a Dun and Bradstreet (DUNS) number to apply for a grant or cooperative agreement from the Federal Government. The DUNS number is a nine-digit identification number, which uniquely identifies business entities. Obtaining a DUNS number is easy and there is no charge. To obtain a DUNS number, access <http://www.dunandbradstreet.com> or call 1-

866-705-5711. Interested parties may wish to obtain their DUNS number by phone to expedite the process.

A DUNS number is required before Central Contractor Registry (CCR) registration can be completed. Many organizations may already have a DUNS number. Please use the number listed above to investigate whether or not your organization has a DUNS number. Registration with the CCR is free of charge.

Applicants may register by calling 1-888-227-2423. Please review and complete the CCR Registration Worksheet located at <http://www.grants.gov/CCRRegister>.

More detailed information regarding these registration processes can be found at <http://www.grants.gov>.

Electronic Research Administration (eRA) User Name

Each NARCH Application's Principal Investigator is required to have a user name with the NIH eRA system. This also requires that the applicant institution (Tribe or Tribal organization) be an eRA Commons Registered Organization. A list of eRA Commons Registered Organizations can be found at http://era.nih.gov/commons/quick_queries/commons_registered_orgs.cfm. More information on the eRA Commons system can be found at <http://era.nih.gov/>.

V. Application Review Information

Upon receipt, IHS and NIH staff will administratively review applications for completeness and responsiveness. Applications that are incomplete, non-responsive to this RFA, or do not follow the guidelines of the PHS form 398 (revised 11/2007) or of the supplementary instructions for NARCH grants (available at: <http://www.ihs.gov/MedicalPrograms/Research/narch.cfm> or from narch@ihs.gov), may be returned to the applicant without further consideration. Applications will be evaluated in accordance with the criteria stated below for scientific and technical merit by appropriate peer review groups convened by the CSR. The National Advisory General Medical Sciences Council will conduct the second level of review.

1. Criteria

Priorities for funding will be based on the scientific and technical merit of the application, the assessed potential of investigators in the developmental stages of their careers, and the likelihood that the proposed project(s) can further the purposes of the NARCH initiative. Awards will be made only to

organizations with financial management systems and management capabilities that are acceptable under HHS policy. Awards will be administered under the HHS Grants Policy Statement, January 2007.

A. Review of Student and Faculty/Researcher Development Plans

The anticipated effectiveness of the proposed NARCH in making a difference relative to the current baseline data (based in part on previous experience of the NARCH) will be assessed. Factors to be considered include:

- The appropriateness of the content, phasing, quality, and duration of the student or faculty/researcher development plans in the NARCH application to achieve the scientific development of the faculty/researcher, post-doctoral, pre-doctoral, undergraduate, and (if well justified) high school students; and
- The research experience and expertise, proposed commitment, and quality of the mentoring plan and of individual mentors of the partners in providing mentoring, guidance, and advice to candidates (including training in responsible conduct of research and research integrity, teaching, and protection of human subjects), and in fostering the development of academic and community-based AI/AN researchers.

B. Review of Research Projects

The NIH has announced procedures to be used for the review of research grant applications (NIH Guide, Volume 26, Number 22, June 27, 1997 or see <http://grants.nih.gov/grants/guide/notice-files/not97-010.html> and <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-05-002.html> for additional updated information.) For NARCH applications, the five criteria listed in this announcement will be used for the scientific review of research projects and pilot research projects. The review of research projects and pilot research projects will be the same except that applications for pilot studies may be smaller in scope and would not be expected to have preliminary data.

In the written comments, reviewers will be asked to discuss the following aspects of the application in order to judge the likelihood that the proposed research will have a substantial impact on the pursuit of these purposes. Each of these criteria will be addressed and considered in assigning the overall score, weighting them as appropriate for each application.

- 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?

- 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?

- 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?

- 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)?

- 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?

In reviewing the overall Center, the initial scientific review group will examine evidence of the partners' commitment to the purposes of the NARCH initiative to develop a cadre of AI/AN scientists and health professionals engaged in biomedical, clinical, behavioral and health services research that is competitive for Federal funding; to increase the capacity of both research-intensive institutions and AI/AN organizations to work in partnership to reduce distrust by AI/AN communities and people toward research; and to encourage competitive research linked to the health priorities of the AI/AN partner and to reducing health disparities.

The evidence will include:

- The quality of the partnership of the institutional and community partners, and the quality of the involvement of the Community and Scientific Advisory Council, as demonstrated by documentation of (for instance): The intellectual and tangible contributions and activities of the partners, and of the

Council, in developing the application and the proposed NARCH; the interactions of the partners, and of the members of the Council, in meetings (such as those to develop the application and proposed NARCH); the past activities and future plans to increase the capacity of the partners and of the Council; the plans for future contributions and activities by the partners, and by the Council, in furthering the goals of the proposed NARCH; and the plans for future development of the partnership itself;

- The experience and commitment of the institutional and community partners to recruit, retain, and advance AI/AN faculty/ researcher and students, to support faculty/researcher and student research efforts, and to increase the role of the involved AI/AN communities in the plans of the proposed NARCH;

- The appropriateness of the plan for evaluating the impact of the proposed NARCH, including the quality of baseline data and milestones for accomplishments, and a system to track the future course of program participants; and

- The potential of the proposed NARCH to be a regional and national resource, including: Capacity to provide quality research training and mentoring for integrated promotion and development of AI/AN research careers from undergraduate (or if well justified, high school) through post-doctoral levels; attainment of quality research linked to health priorities of the AI/AN partner and to reducing health disparities; plans for research information dissemination and education activities; and plans for the development of research networks to support the scientific aims of the proposed NARCH. For competitive renewal applications, reviewers will also assess the previous accomplishments and progress of the applicants.

In addition to the above criteria, in accordance with NIH policy, all applications will also be reviewed with respect to the following:

- The adequacy of plans, if research on human subjects is involved, to include both genders and children as appropriate for the scientific goals of the research. Plans for the recruitment and retention of subjects will also be evaluated.

- For applications that are competing renewals of existing NARCH centers, has significant progress been achieved toward each of the originally proposed projects?

- The reasonableness of the proposed budget and duration in relation to the proposed research.

- The adequacy of the proposed protection for humans, animals or the environment, to the extent they may be adversely affected by the project proposed in the application.

- The adequacy of the proposed plan to share data, if appropriate.

VI. Award Administration Information

1. Award Notices

The Notice of Award (NoA) will be initiated by the IHS Division of Grants Operations (DGO) and will be mailed via postal mail to each entity that is approved for funding under this announcement. The NoA will be signed by the Grants Management Officer and this is the authorizing document for which funds are dispersed to the approved entities. The NoA will serve as the official notification of the grant award and will reflect the amount of Federal funds awarded, the purpose of the grant, the terms and conditions of the award, the effective date of the award, and the budget/project period. The NoA is a legally binding document. Applicants who are approved but unfunded or disapproved based on their objective review score will receive a copy of the Executive Summary which identifies the weaknesses and strengths of the application submitted.

2. Administrative and Policy Requirements

A. Grants are administrated in accordance with the following documents:

- This Announcement.
- Administrative Requirements: 45 CFR part 92, (Uniform Administrative Requirements for Grants and Cooperative Agreements to State, Local and Tribal Governments, (or 45 CFR part 74, (Uniform Administrative Requirements for Awards to Institutions of Higher Education, Hospitals, Other Non-Profit Organizations, and Commercial Organizations.
- Grants Policy Guidance: HHS Grants Policy Statement, January 2007.
- Cost Principles: OMB Circular A-87, (State, Local, and Indian (Title 2 Part 225).
- Cost Principles: OMB Circular A-122, (Non-profit Organizations (Title 2 Part 230).
- Audit Requirements: OMB Circular A-133, (Audits of States, Local Governments, and Non-profit Organizations).

B. Inclusion of Women and Minorities in Research Involving Human Subjects:

It is the policy of the NIH that women and members of minority groups and

their subpopulations must be included in all NIH supported biomedical, clinical, behavioral, and health services research projects involving human subjects, unless a clear and compelling rationale and justification is provided 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 Pub. L. 103-43). Because the NARCH initiative targets AI/AN people and communities, a minority population, only the policy of inclusion of women applies to this RFA. The IHS has fully accepted the Office for Human Research Protections (OHRP) policy regarding human subjects. The OHRP Web site is <http://www.hhs.gov/ohrp/>. All investigators proposing research involving human subjects should read the Updated NIH Guidelines for Inclusion of Women and Minorities as Subjects in Clinical Research, published in the NIH Guide for Grants and Contracts on August 2, 2000. (<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-048.html>). The complete Guidelines are available at: http://grants1.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm. The revisions relate to NIH defined Phase III clinical trials and require:

- All applications or proposals and/or protocols to 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
- All investigators to report accrual, and to conduct and report analyses, as appropriate, by sex/gender and/or racial/ethnic group differences.

C. Inclusion of Children as Participants in Research Involving Human Subjects

It is the policy of NIH that children (i.e., individuals under the age of 21) must be included in all human subjects research, conducted or supported by the NIH, unless there are scientific or ethical reasons not to include them. This policy applies to all initial (Type 1) applications submitted. 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 was published in the NIH Guide for Grants and Contracts, March 6, 1998, and is available at the following URL address: <http://grants.nih.gov/grants/guide/notice-files/not98-024.html>.

Investigators may obtain copies of these policies from the initiative staff listed under VII. Agency Contacts. Initiative staff may also provide additional

relevant information concerning the policy.

D. 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. Reviewers are cautioned that their anonymity may be compromised when they directly access an Internet site.

E. Allowable Administrative Costs

Certain administrative costs for managing a comprehensive program are allowable and may vary, depending upon the size and complexity of the program's activities. The costs budgeted for NARCH grants and subcontracts may not duplicate items already budgeted in other cost centers of the AI/AN, research-intensive, and subcontracted organizations and institutions, such as accounts which make up the Facilities and Administration (F&A) cost pool. The grantee organization receiving the award must be prepared to provide documentation showing the direct relationship of proposed costs to the program, and that costs of this type are charged in a uniform manner to all other grants at all institutions and organizations participating in the award.

Limited salary support for secretarial or clerical help is allowable only when in direct support of the proposed NARCH project. For guidance, applicants should refer to the OMB Circular appropriate for them, A-87 (Cost Principles for State, local, and Indian Tribal Governments), at <http://www.whitehouse.gov/omb/circulars/A-87> (Cost Principles for Non-Profit Organizations), at <http://frwebgate.access.gpo.gov/cgi-bin/leaving.cgi?from=leavingFR.html&log=linklog&to=http://http://www.whitehouse.gov/omb/circulars/A-122> (Cost Principles for Non-Profit Organizations), at <http://frwebgate.access.gpo.gov/cgi-bin/leaving.cgi?from=leavingFR.html&log=linklog&to=http://http://www.whitehouse.gov/omb/circulars/A-122> (Cost Principles for Non-Profit Organizations), or should contact the Grants Management Officer listed under VII. Agency Contacts.

Costs for evaluation activities are allowable, as are costs for the Community and Scientific Advisory Council. All research project applications must include costs associated with one annual meeting per year in Rockville, MD, of the project Principal Investigator(s) and their key scientific personnel. Research project applications should also include costs associated with attendance for key personnel and presenters to the annual

Native Health Research Conference. NARCH core and/or training budgets should include these travel costs for key NARCH personnel and trainees who are not associated with specific research projects.

Student Development Costs: Student (graduate, undergraduate, and high school if well justified) remuneration through salary/wages for participation in research experiences may be requested, provided all the following conditions are met:

- I. The student is performing necessary work involved in the research;
- II. There is an employer-employee relationship between the student and the proposed NARCH or its partners;
- III. The total compensation is reasonable for the work performed; and
- IV. It is the practice of the proposed NARCH or its partners to provide compensation for all students in similar circumstances, regardless of the source of support for the activity.

Graduate students, but not undergraduate students, are allowed tuition costs as part of a compensation package. When requesting support for a graduate student, the NARCH application should provide, in the budget justification section of the application, the basis for the compensation level. The IHS staff will review the requested compensation level and, if it is reasonable and justified, will provide compensation up to a maximum of \$45,000 (<http://grants.nih.gov/grants/guide/notice-files/not98-168.html>). Post-doctoral students should be compensated at a rate commensurate with that of other post-doctoral employees with similar degrees and experience at the research-intensive institution. It is the expectation of the IHS and NIGMS that students who are enrolled in an accredited graduate program, as part of a proposed NARCH, will not be excluded from support from other non-Federal or Federal graduate training sources (such as loans and assistance under the Veterans' Adjustment Benefit Act or Pell Grants) for which they are eligible.

Graduate and post-doctoral students cannot concurrently hold other Federally-sponsored stipends or fellowship or any other Federal award that duplicates the NARCH support.

Faculty/Researcher Development Costs

Costs to support faculty/researcher development activities, such as workshops or courses, national meetings, or short-term research experiences in the laboratory of an active NIH-extramurally-funded researcher needed for acquiring specific skills or methodologies needed for

prospective research, are allowable. Such costs might include tuition, travel and per diem costs, as well as salary support appropriate to the percent effort needed for the activity.

Research Project Costs

Direct costs associated with research and pilot research projects are allowable when adequate justification is provided. These include faculty/researcher salaries, reimbursed according to percent effort. Summer salary support can be paid provided the institution's academic schedule permits such release and when the institution approves. The maximum summer-salary support provided by the program cannot exceed the equivalent of three months at 100 percent effort, or time specified by the institution as its policy. Grant funds may not be used to increase or supplement faculty/researcher academic year salaries. Salary support for technical assistance and costs for consultants, if justified, are allowable. Costs for equipment to be used to carry out the proposed research are allowable.

Cost for Supplies

Costs for supplies, including costs for animals necessary to carry out the proposed research, may be included. Travel costs for the investigator(s) and staff are permitted to required meetings or when direct benefits to the program are expected, and when adequate justification is provided. Alterations and renovations costs (up to \$40,000) are allowable only when essential for conduct of the proposed research. Other permitted costs include animal maintenance (unit care costs and number of care days), donor fees, publication costs, computer charges, rentals and leases, equipment maintenance, and service contracts.

Consortium and Contract Arrangements

Consortium arrangements that may involve personnel costs, supplies, and other allowable costs, including overhead costs; contractual costs for support services, such as the laboratory testing of biological materials, clinical services, data processing, or core administrative services, are allowable expenses. Consortia and contractual costs with Native health organizations, Tribes and/or research institutions in Canada or Mexico are allowable expenses.

Pilot Research Projects

The intent of pilot research projects is to lead to regular research projects funded as part of the center grant or as freestanding grants. For pilot research projects, applications may request

support for up to \$75,000 (direct costs) per year for up to four years. Pilot research investigators considering project periods of less than four years are encouraged to consider the fact that initiation of a new research activity in a new population often takes much longer than originally anticipated and that the creation of a trusting relationship between the investigator and the community is both vital and time consuming. NARCH pilot research support is non-renewable. However, NARCH research projects based on prior NARCH pilot research projects are encouraged.

Subcontracts

The grant recipient may issue subcontracts to other organizations (such as the research-intensive institution of the partnership), as long as a minimum of 30 percent of the grant funds are budgeted in the application to remain with the eligible AI/AN organization(s); that is, no more than 70 percent of the application's total budget may be contained in subcontract budgets of the non-eligible subcontracting partner institutions or organizations.

F. Unallowable Costs

Unallowable costs for research projects (including for pilot projects) include costs for student development, textbooks, journals, memberships, and Internet subscription costs, as well as other costs prohibited by OMB Circulars A-87 or A-122 as applicable. Employees of the applicant organization may not serve as paid consultants but may be paid. The pilot research project is intended for faculty/researcher without current Federal research support. Therefore, investigators with significant current support from other mechanisms such as the R01 and research funding from other extramural sources are not eligible, and the costs therefore are not allowable. Release time for preparing proposals or mini-research projects, not submitted as pilot projects, is not allowed.

G. Research Subjects Protection

Under governing policy, Federal funds administered by the HHS shall not be expended for research involving live vertebrate animals without prior approval by the NIH Office of Laboratory Animal Welfare (OLAW), of an assurance to comply with the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals. This restriction applies to all performance sites (e.g., collaborating institutions, subcontractors, subgrantees) without OLAW-approved

assurances, whether domestic or foreign. Funds included in this award may not be used to support studies using live vertebrate animals until approval from the Institutional Animal Care and Use Committee (IACUC) has been received by the IHS Grants Management Officer (GMO).

Federal Regulations (45 CFR, Part 46) 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. Under governing regulations 45 CFR part 46, found at <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm>, Federal funds administered by HHS shall not be expended for research involving human subjects, and individuals shall not be enrolled in such research, without prior approval by the Office for Human Research Protections (OHRP), of an appropriate Federal Wide Assurance (FWA) and prior approval by an Institutional Review Board (IRB) recognized and listed by the OHRP. Funds included in this award may not be used to support studies using human subjects until evidence of IRB approval has been received by the IHS GMO. Grantees are expected to provide their own institutional FWA.

H. Research Integrity

Grantees shall comply with Public Health Service Policies on Research Misconduct (42 CFR part 93) which require grantees to have procedures for responding to allegations of research misconduct that comply with those policies, to submit their procedures to the Office of Research Integrity (ORI) (<http://ori.hhs.gov>) upon request for review, and revise their procedures in accordance with ORI comments. In addition, grantees shall file the Annual Report on Possible Research Misconduct with ORI at http://www.ori.dhhs.gov/assurance/electronic_submission.shtml.

Grantees shall file documentation of their Annual Reports with the IHS GMO.

I. 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 RFA announcement is related to one or more of the priority areas. Potential applicants may obtain a copy of Healthy People 2010 at: <http://www.healthypeople.gov>.

3. Indirect Costs

This section applies to all grant recipients that request reimbursement of indirect costs in their grant application, but not to the indirect costs that may be negotiated by the grantees with their subcontractors (which become direct costs to the grantee). In accordance with HHS Grants Policy Statement, Part II-27, IHS requires applicants to have a current indirect cost rate agreement in place prior to award. The rate agreement must be prepared in accordance with the applicable cost principles and guidance as provided by the cognizant agency or office. A current rate means the rate covering the applicable activities and the award budget period. If the current rate is not on file with the DGO at the time of award, the indirect cost portion of the budget will be restricted and not available to the recipient until the current rate documentation is provided to the DGO.

Generally, indirect costs rates for IHS grantees are negotiated with the Division of Cost Allocation <http://rates.psc.gov/> and/or the Department of the Interior (National Business Center) <http://www.nbc.gov/acquisition/ics/icshome.html>. If your organization has questions regarding the indirect cost policy, please contact the DGO at (301) 443-5204.

4. Reporting

A. Progress Report. Program progress reports are required semi-annually. These reports will include a brief comparison of actual accomplishments to the goals established for the period, or, if applicable, provide sound justification for the lack of progress, and other pertinent information as required. A final annual progress report, cumulative from the beginning of the project period, must be submitted within 90 days of expiration of each budget period.

B. Financial Status Report. Quarterly financial status reports must be submitted within 30 days of the end of each quarter. Final financial status reports are due within 90 days of expiration of the budget/project period. Standard Form 269 (long form) will be used for financial reporting.

C. Reports. Grantees are responsible and accountable for accurate reporting of the Progress Reports and Financial Status Reports. Financial Status Reports (SF-269) are due 90 days after each budget period and the final SF-269 must be verified from the grantee records on how the value was derived. Grantees must submit reports in a reasonable period of time.

Failure to submit required reports within the time allowed may result in

suspension or termination of an active grant, withholding of additional awards for the project, or other enforcement actions such as withholding of payments or converting to the reimbursement method of payment. Continued failure to submit required reports may result in one or both of the following: (1) The imposition of special award provisions; and (2) the non-funding or non-award of other eligible projects or activities. This applies whether the delinquency is attributable to the failure of the grantee organization or the individual responsible for preparation of the reports.

5. Telecommunication for the Hearing Impaired is Available at: TTY (301) 443-6394.

VII. Agency Contact(s)

1. Questions on the initiative regarding IHS NARCH issues and policies may be directed to: Alan Trachtenberg, M.D., M.P.H., Division of Planning, Evaluation and Research, Indian Health Service, 801 Thompson Avenue, TMP Suite 450, Rockville, MD 20852, Phone: (301) 443-4700, Fax: (301) 443-0114, e-mail: narch@ihs.gov.

2. Questions on grants management and fiscal matters may be directed to: Sylvia Ryan, Division of Grants Operations, Indian Health Service, Reyes Building, 801 Thompson Avenue, TMP Suite 350, Rockville, MD 20852, Phone: (301) 443-5204, Fax: (301) 443-9602, e-mail: narch@ihs.gov.

3. Questions on NIH and NIGMS issues and policies, may be directed to: Clifton A. Poodry, Ph.D., Minority Opportunities in Research Division, National Institute of General Medical Sciences, 45 Center Drive, Suite 2AS.37, MSC 6200, Bethesda, MD 20892, Phone:

(301) 594-3900, Fax: (301) 480-2753, e-mail: poodryc@nigms.nih.gov.

4. Questions on the review of applications may be directed to: Mushtaq A. Khan, D.V.M., Ph.D., Chief, Digestive and Respiratory Sciences IRGs, Center for Scientific Review, MSC 7818, Room 2176; 6701 Rockledge Drive; Bethesda, MD 20892 (20817 for courier or express service) Phone: (301) 435-1778; Fax: (301) 451-2043; e-mail: khanm@csr.nih.gov.

VIII. Other Required Documents

If the applicant is a federally-recognized Tribe, Tribal organization, or a Tribal college, letters of support from the Chairman, President, Governor, or Tribal Health Director is required of all Tribes to be served to show their support of the grant project. Letters of support are intended to document that applicants have Tribal support for the specific grant for which they are applying. All letters of support must accompany the grant application.

IX. Other Information

References for Background Information:

Anderson, N.B. Levels of analysis in health science: A framework for integrating sociobehavioral and biomedical research. *Annals of the New York Academy of Sciences*, 1998, 840, 563-576.

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