or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of Patents and Trademarks may award (for example, half the testing phase must be subtracted, as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product GEODON (ziprasidone hydrochloride). GEODON is indicated for the treatment of schizophrenia. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for GEODON (U.S. Patent No. 4,831,031) from Pfizer, Inc., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated July 16, 2003, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of GEODON represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for GEODON is 3,933 days. Of this time, 2,511 days occurred during the testing phase of the regulatory review period, while 1,422 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(i) became effective*: May 3, 1990. FDA has verified the applicant's claim that the date the Investigational New Drug application became effective was on May 3, 1990.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the act*: March 17, 1997. FDA has verified the applicant's claim that the new drug application (NDA) for GEODON (NDA 20–825) was initially submitted on March 17, 1997.

3. *The date the application was approved*: February 5, 2001. FDA has verified the applicant's claim that NDA 20–825 was approved on February 5, 2001.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,825 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments and ask for a redetermination by June 28, 2005. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by October 26, 2005. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Division of Dockets Management. Three copies of any mailed information are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 5, 2005.

Jane A. Axelrad,

Associate Director for Policy, Center for Drug Evaluation and Research.

[FR Doc. 05–8587 Filed 4–28–05; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Native American Research Centers for Health (NARCH) Grants

Announcement Type: New.

Funding Opportunity Announcement: HHS–2005–IHS–NARCH–0001.

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

Key Dates: Release Date: May 2005. Letter of Intent Deadline: August 1, 2005. Application Deadline Date: September 14, 2005. Review Date: November 2005. Earliest Anticipated Start Date: June 1, 2006.

Due Dates for E.O. 12372: Not Applicable.

Summary

The Indian Health Service (IHS), with the National Institute of General Medical Sciences (NIGMS) of the National Institutes of Health announces an initiative to support the Native American Research Centers for Health (NARCH) grant. This funding mechanism will develop opportunities for conducting research and research training to meet the needs of American Indian/Alaska Native (AI/AN) communities. The estimated funds (total costs) available for the first year of support for the entire initiative is expected to be over $2.2 million in FY 2006. The actual amount may vary, depending on the response to the Request for Applications (RFA) and the availability of funds. Eligibles include federally-recognized Indian Tribes, Tribally sanctioned non-profit Tribal organizations, Non-profit national or area Indian health boards, and consortiums of two or more of those Tribes, Tribal organizations, or health boards.

I. Funding Opportunity Description

Purpose of the RFA

The NARCH initiative will support partnerships between AI/AN Tribes or Tribally-based organizations such as the National Indian Health Board and Area Health Boards, and institutions that conduct intensive academic-level biomedical, behavioral and health services research. These partnerships are called Native American Research Centers for Health (NARCH). The purposes of the NARCH initiative are:

1. To develop a cadre of AI/AN scientists and health professionals engaged in biomedical, clinical, behavioral and health services research who will be competitive in securing

National Institutes of Health (NIH) funding;

2. 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

3. To encourage competitive research linked to the health priorities of the AI/AN organizations and to reducing health disparities. These purposes will be achieved by supporting student development projects, faculty/researcher development projects, and research projects (including pilot projects) developed by each NARCH partnership.

Background

The AI/AN Tribal nations and communities have long experienced poorer health status than other Americans. Although major gains of reducing health disparities were made in 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); 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/publicInfo/publications/index.asp.* Although the ''All Indian'' 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 up to 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 research relevant to improve their health status. Many AI/ANs distrust research for historical reasons. One approach that combats this distrust is to ensure that Tribes are senior partners in training and research that involves them, as for example in community-based participatory research. 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: 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 Board, the IHS NARCH program will pursue the following program objectives:

A. To Develop a Cadre of AI/AN Scientists and Health Professionals—Offering opportunities 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.

B. To Enhance Partnerships—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.

C. To Reduce Health Disparities—In the amended Indian Health Care Improvement Act, Public Law (Pub. L.) 94–437, 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 Native American Research Centers for Health.

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 also have 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 train and promote researchers concerned with AI/AN health.

II. Award Information

1. Mechanism(s) of Support

Awards under this initiative will be administered using the competing institutional grant mechanism of the IHS. This funding opportunity will be

reviewed using the NIH SO6 mechanisms. The responsibility for planning, directing, and executing the program, as well as data acquisition and analysis and evaluation of the proposed program, lies with the applicant organization.

2. Funds Available

The estimated funds (total costs) available for the first year of support for the entire initiative is expected to be over $ 2.2 million in Fiscal Year 2006. The actual amount may vary, depending on the response to the RFA and availability of funds. An application may request a project period not to exceed four years of support, and direct costs not to exceed $800,000 in the first year. Direct costs to the applicant include the entire cost of each subcontract—that is, each subcontract's direct cost plus the subcontract's appropriate Facilities and Administration (F&A) cost. Because it is anticipated that all budget requests will exceed $250,000, the modular grant requirements would not apply to this RFA.

The maximum grant period may not exceed four years, with the opportunity for a competing renewal at the end of that period.

III. Eligibility Information

The proposed NARCH must be a working partnership of the AI/AN organization and of the research-intensive institution. Applicants eligible to receive a NARCH award are the AI/AN organizations of the partnerships. As the grantee, the 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 remain with that AI/AN organization, that is, no more than 70 percent may be subcontracted to other institutions or organizations.

1. Eligible Applicants

The AI/AN applicant must be one of the following:

A. A federally recognized Indian Tribe; or

B. A Tribally sanctioned non-profit Tribal organization; or

C. A non-profit national or area Indian health board; or

D. A consortium of two or more of those Tribes, Tribal organizations, or health boards.

2. Cost Sharing or Matching

Cost sharing or matching is not required.

3. Other Requirements

A. The Research-Intensive Partner

The Research-Intensive Partner must be an accredited public or private nonprofit university 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.

B. 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.

C. 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.

D. Student and Faculty/Researcher Development Director and Participants

The NARCH initiative is an institutional developmental grant mechanism that places an emphasis on the continual development of students and faculty/researchers. 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 other consortium partner.

E. 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 proposed 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.

F. 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 a federally recognized Indian Tribe—a resolution of support from the Tribal government must be part of the application. Applications that involve more than one Indian Tribe must include resolutions of support from all participating Tribes. For an eligible consortium of Tribes—a resolution of support from each Tribe of the consortium must be included.
- For a Tribally sanctioned non-profit Tribal organization—specific Tribal resolution(s) of support will not be required if the current Tribal resolution(s) under which the organization operates encompasses the proposed application. (A copy of the current operational resolution(s) must be submitted with the application.)

An official signed resolution must be received by the Division of Grants Operations, IHS, at the Reyes Building, 801 Thompson Avenue, TMP 100, Rockville, MD 20852. A grant will not be awarded unless the signed resolution is received.

For a Non-profit national or area Indian health board, or a consortium of those eligible Indian health boards—a

resolution is not required. However, the applicant organization must submit a letter of support signed by the executive director of each health board involved, specifically citing the research project proposed. Each AI/AN organization that derives benefit from the grant must also submit such a letter.

G. 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. Applicants are strongly encouraged to establish eligibility of their proposed applications prior to submission. Inquiries about eligibility should be addressed to Timothy L. Taylor, Ph.D., at (301) 443–1549. The application package will be posted on the IHS Research Program Web site, at: *http://www.ihs.gov/MedicalPrograms/Research/narch.cfm*.

The NIH PHS 398 application instructions are available at: *http://grants.nih.gov/grants/funding/phs398/phs398.html* in an interactive format. 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.

There will be no acknowledgment of receipt of the application.

2. Content and Form of Application Submission

A. 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 facility.

B. 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. 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 to contribute to the success of the NARCH.

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 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*.

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*.

''DUNS'' Number

Applications must be prepared using the PHS 398 research grant application instructions and forms (revised 9/2004). As of October 1, 2003, applications must have a Dun and Bradstreet (D&B) Data Universal Numbering System (DUNS) number as the Universal Identifier when applying for Federal grants or cooperative agreements. The DUNS number can be obtained by calling (866) 705–5711 or through the Web site at *http://www.dunandbradstreet.com/*. The DUNS number should be entered on line 11 of the face page of the PHS 398 form. The PHS 398 document is available at *http://grants.nih.gov/grants/funding/phs398/phs398.html* in an interactive format. For further assistance contact Grants Info, Telephone (301) 435–0714, e-mail: *GrantsInfo@nih.gov*. Internet applications for a DUNS number can take up to 30 days and this could cause organizations to lose opportunities to apply, or delay them until the next round. It is significantly faster to obtain one by phone. You will need the following information to request a DUNS number:

- Organization name.
- Organization address.
- Organization telephone number.
- Name of CEO, Executive Director, President, *etc.* (The person in charge.)
- Legal structure of the organization.
- Year organization started.
- Primary business (activity) line.
- Total number of employees.

C. The RFA label available at *http://grants1.nih.gov/grants/funding/phs398/label-bk.pdf* in the PDF format, must be affixed to the bottom-face page of the application. Type this RFA number: ''NOT GM–04–107'' on the label. Failure to use this label could delay processing the application and it may not reach the review committee in time for review. In addition, the ''Native American Research Centers for Health'' and the RFA number must be typed on line 2 of the face page of the application form and the YES box must be marked.

D. If Student Development Projects are proposed, the NARCH application should describe new programs, modifications or additions to existing programs of the partners that encourage and facilitate AI/AN students to enter, advance, and remain in 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 student will meet both the individual's 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 project(s) that indicates the anticipated outcomes relative to the current baseline data. For example, one outcome might be the improved retention of students in science majors. The application should indicate the anticipated (quantitative) improvement relative to the current retention rate.

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*.

E. 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 individual's 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.

F. 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 $50,000 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 [AREA], 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.

Research projects (including pilot research projects) proposed under this initiative must be in research areas normally funded by any of the National Institutes of Health. 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 CRISP (Computer Retrieval of Information on Scientific Projects), a searchable database of federally funded biomedical research projects conducted at universities, hospitals, and other research institutions. It may be accessed at (*http://ott.od.nih.gov/crisp.html*).

Each research project or pilot research project should follow the instructions provided in PHS 398 (revised 9/2004) 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 director 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 non-profit organization.

3. Submission Dates and Times

A. Letter of Intent Deadline: August 1, 2005.

Prospective applicants are asked to submit a letter of intent that includes the title of the proposed NARCH, the name, address, and telephone number of the Principal Investigator and its Program Director, 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 6 p.m. EST on May 1, 2005, 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 Fed Ex)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: September 14, 2005.

The applications must be received before 6 p.m. EST on September 14, 2005. If an application is received after that date, it will be returned to the applicant without review. To be considered timely, an application must be sent on or before the deadline date. If sent timely (with documented proof of mailing) but received after the deadline, an application will be accepted for review only if it is received in time for orderly processing. Competing applications not meeting the deadline date specified in the announcement are considered late applications and will not be considered for funding under that announcement. The Center for Scientific Review (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 introduction 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

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 Requirement

The administrative personnel, facilities, and programs of the overall NARCH should be described. It is permissible, but not necessary to have a set of core support programs that provide common scientific services to two or more NARCH projects. 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: Grants Management Branch, Indian Health Service, Reyes Building, 801 Thompson Avenue, TMP 100, Rockville, MD 20852–1627 (zip code is unchanged for express/courier services), Telephone: (301) 443–5204.

Also, at the time of submission, send four (4) 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). Telephone: (301) 435–0715.

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 9/2004) or of the supplementary instructions for NARCH grants, will 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 NARCH 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 PHS policy. Awards will be administered under the PHS Grants Policy Statement.

2. Review and Selection Process

A. Review of Student and Faculty/Researcher Development Plans

The anticipated effectiveness of the proposed NARCH in making a difference relative to the current base-line data (based in part on previous experience of the partners) 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; andThe experience, 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 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.

• 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.

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.

3. Anticipated Announcement and Award Dates

Anticipated Announcement Date: May 2005.

Earliest Anticipated Award Date: June 1, 2006.

VI. Award Administration Information

1. Award Notices

Grants Management will not award a grant without an approved application in conformance with regulatory and policy requirements and which describes the purpose and scope of the project to be funded. When the application is approved for funding, the Grants Management Office will prepare a Notice of Grant Award with special terms and conditions binding upon the award and refer to all general terms applicable to the award.

2. Administrative and National Policy Requirements

Authority and Regulations

This program is described in the Catalog of Federal Domestic Assistance at: *http://www.cfda.gov/* and is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review. Awards are made under the authorization of 301(A) and 405 of the Public Health Service Act. Awards will be subject to OMB Circulars, HHS Grant Regulations at 45 CFR Parts 74 and 92. The grant will be administered under the PHS Grants Policy Statement and other applicable agency policies, IHS and NIH policies and procedures. Also, see Senate Appropriations Committee Report, No. 92–316, July 29, 1971, Executive Order 12900, Educational Excellence for Hispanic Americans February 22, 1994, Executive Order 12876, Historically Black Colleges and Universities, November 1, 1993, and Executive Order 13021, October 21, 1996, and Outline of Work Plan, August 18, 1998, White House Initiative on Tribal Colleges and Universities. Applications are not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

A. 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 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.

B. 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 Contact. Initiative staff may also provide additional relevant information concerning the policy.

C. 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.

D. Public Access To Research Data Through the Freedom of Information Act

The OMB Circular A–110 has been revised to provide public access to research data through the Freedom of Information Act (FOIA) under some circumstances. Data that are:

• First produced in a project that is supported in whole or in part with Federal funds; and

• Cited publicly and officially by a Federal agency in support of an action that has the force and effect of law (*i.e.*, a regulation) may be accessed through FOIA.

It is important for applicants to understand the basic scope of this amendment. NIH has provided guidance at: *http://grants.nih.gov/grants/policy/a110/a110_guidance_dec1999.htm*. Applicants may wish to place data collected under this RFA in a public archive, which can provide protections for the data and manage the distribution for an indefinite period of time. If so, the application should include a description of the archiving plan in the study design and include information about this in the budget justification section of the application. In addition, applicants should think about how to structure informed consent statements and other human subjects procedures given the potential for wider use of data collected under this award.

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.

Salary (up to 25 percent effort, although it should generally be less) for the NARCH Program Director is allowable for that portion of time or effort specifically employed in directing the proposed NARCH. (The 25 percent limit does not include salary for being a research investigator.) Limited salary support for secretarial or clerical help is allowable only when in direct support of the proposed NARCH. 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* or A–122 (Cost Principles for Non-Profit Organizations), *http://www.whitehouse.gov/omb/circulars*, 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 applications must include costs associated with one annual meeting per year in Rockville, MD, of NARCH directors and their key scientific personnel. Applications should also include costs associated with attendance at the annual IHS Research conference for key personnel and trainees.

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:

• The student is performing necessary work involved in the research.

• There is an employer-employee relationship between the student and the proposed NARCH or its partners.

• The total compensation is reasonable for the work performed.

• 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 a 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 another federally-sponsored stipend 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.

Costs for Core Scientific Services:

Costs for core scientific services to support two or more projects are allowable. Costs for multi-user research equipment are also allowable. A plan for access to the multi-user equipment, its maintenance, management and use must be included. To aid in the review, it is suggested that a tabular summary show the estimated or actual proportional use of this equipment by each project, and other investigators and students. Justify this core component by discussing ways in which these centralized services improve quality, bring about an economy of effort, and/or save overall costs as compared to their inclusion as part of each research project. Personnel costs to maintain and service the equipment are an allowable cost. Support for very large pieces of equipment, however, may be restricted by the NARCH budget. Plans to maintain the shared core scientific services and facility beyond the grant period should be discussed.

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) are permitted 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 F&A 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 $50,000 (direct costs) per year. This support is non-renewable.

Subcontracts:

The grant recipient may issue subcontracts to other organizations (such as the research-intensive institution of the partnership), as long as at least 30 percent of the grant remains with the AI/AN organization; that is, no more than 70 percent may be subcontracted.

F. Unallowable Costs

Unallowable costs for research projects (including for pilots 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. Qualifications of the NARCH Program Director and Key Personnel

As leader of the research and research training for the proposed NARCH, the NARCH Program Director is expected to possess certain essential qualifications such as:

- Strong leadership skills, including scientific leadership experience and a strong academic and scientific background, as exemplified, ideally, by scientific publications and a record of peer-reviewed scientific support;
- Knowledge of and personal working relationship with the AI/AN Tribes or communities involved in the NARCH research, and with the partners of the proposed NARCH;
- Strong mentoring and supervision skills, to exercise responsibility for mentoring activities, organization of communicating skills programs, special methods workshops, tracking of student career plans, etc.; and
- Knowledge of IHS and NIH policies, including those concerning human participants in research, human biological material, animals, hazardous materials, and Tribal review and approval of research.

The names and qualifications of the NARCH Program Director, the Student and Faculty/Researcher Development Director and directors of individual projects within the program (where appropriate), and any other key personnel, should be listed in the application under the Key Personnel section. Biographical Sketches of these individuals, including other grant support, should be included.

H. Human Subjects Protection

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 (*http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm*)

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 Request for Application (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. Reporting

The NARCH Program Office and Grants Management have requirements for the progress reports and financial reports based on the terms and conditions of the grant. Grantees are responsible and accountable for accurate reporting of the Progress Reports and Financial Status Reports which are generally due annually. 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 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.

VII. Agency Contact(s)

1. Questions on the initiative, regarding IHS NARCH issues and policies, may be directed to: Timothy L. Taylor, Ph.D., Director of Planning, Evaluation and Research, Indian Health Service, 801 Thompson Avenue, TMP, Suite 450, Rockville, MD 20852–1750, Telephone: (301) 443–0222, Fax: (301) 443–1522, e-mail: *ttaylor@hqe.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, Rockville, MD 20852–1627, Telephone: (301) 443–5204, Fax: (301) 443–9602, e-mail: *sryan@hqe.ihs.gov*.

3. Questions on 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 20892–6200, Telephone: (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 Fed Ex) Telephone: (301) 435–1778; Fax: (301) 451–2043; e-mail: *khanm@csr.nih.gov*.

VIII. Other Information

Technical Assistance Workshops

The IHS and NIH intend to conduct technical assistance and information sharing workshops about this grant initiative in July 2005 at one regional center. Potential grantees wanting to attend one of these workshops will have to provide names and the eligible organization to Ms. Sylvia Ryan, at telephone number (301) 443–5204 or Fax (301) 443–9602, or by e-mail to *sryan@hqe.ihs.gov* as soon as possible and no later than March 15, 2005. This notification will help the IHS and the NIH to determine the best times and locations for potential grantees' training and to have adequate workshop supplies. The details of the workshops and locations will be posted (as they are finalized) on the IHS Research Program Web site at *http://www.ihs.gov/medicalprograms/research*.

References for Background Information

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Dated: April 22, 2005.

Charles Grim,

Assistant Surgeon General Director, Indian Health Service.

[FR Doc. 05–8465 Filed 4–28–05; 8:45 am]

BILLING CODE 4165–16–U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, DHHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

ADDRESSES: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: (301) 496–7057; fax: (301) 402–0220. A signed